01-17-07

AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): William BEDINGHAM et al. Group Art Unit: 2856

Serial No.: 10/734,717 Examiner: Robert R. Raevis

Confirmation No.: 2357

Filed: 12 December 2003 Docket No.: 59071US002

Title: VARIABLE VALVE APPARATUS AND METHODS

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X An itemized return postcard.

___ A Petition for Extension of Time for __ month(s). Please charge Deposit Account No. 13-4895 in the amount of $___ for the required fee.

___ An Information Disclosure Statement (__ pgs); copies of ___ applications; 1449 forms (__ pgs); and copies of ___ documents cited on the 1449 forms.

__ A request for continued examination (RCE). Please charge Deposit Account No. 13-4895 in the amount of $_____, for the required filing fee.

X An Appeal Brief (17 pgs); Claims Appendix (11 pgs); Evidence Appendix (155 pgs); Related Proceedings Appendix (1 pg): and Cited Authorities and Documents (50 pgs). Please charge Deposit Account No. 13-4895 in the amount of $500.00, for the required Appeal Brief filing fee.

__ A check in the amount of $___, for __.

___ A certified copy of a __ application, Serial No. __, filed _____, the right of priority of which is claimed under 35 U.S.C. §119.

__ Amendment ___ No Additional fee is required. __ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $50 =	
Independent Claims				x $200 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $360 Here →					
				Total Additional Claim Fees Required	

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: KWR
Name: Kevin W. Raasch
Reg. No.: 35,651
Direct Dial: 612-305-1218
Facsimile: 612-305-1228

CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 201 878 095 US Date of Deposit: January 16, 2007
I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to: **Mail Stop Appeal Brief - Patents,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
By: Deb Schurmann Name: Deb Schurmann

(LARGE ENTITY TRANSMITTAL UNDER RULE 1.10)

PATENT
Docket No. 59071US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	William BEDINGHAM et al.	Group Art Unit:	2856
Serial No.:	10/734,717	Examiner:	Robert R. Raevis
Confirmation No.:	2357		
Filed:	12 December 2003		
For:	VARIABLE VALVE APPARATUS AND METHODS		

APPEAL BRIEF

Commissioner for Patents
Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is presented in support of the Appeal filed 16 November, from the final rejection of claims 1-9 and 11-30 of the above-identified application under 37 C.F.R. §§1.113 and 1.191.

This Brief is being submitted as set forth in 37 C.F.R. § 41.37. Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. § 41.20(b)(2).

I. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, 3M Innovative Properties Company evidenced by an Assignment recorded 12 December 2003, at reel 14812 and frame 6050/52.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to Appellant's Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-9 and 11-30 are pending and are the subject of this appeal (see Claim Appendix).

IV. STATUS OF AMENDMENTS.

Appellants submitted an amendment to claim 26 in a response to the Final Office Action that was filed on October 24, 2006. As indicated in the Advisory Action issued on November 6, 2006 (copy attached in Evidence Appendix), the amendment to claim 26 was entered. Claim 26 as amended is, therefore, included in the claims presented in the Claim Appendix attached hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER.

The following is a summary of Appellants' invention as recited in independent claims 1, 13, 14, 22, and 23, as well as a summary of various embodiments of the invention as recited in claims dependent thereto.

Appellants' invention, as recited in independent claim 1, is directed to a valved process chamber on a sample processing device, the valved process chamber including a process chamber having a process chamber volume located between opposing first and second major sides of the sample processing device. The process chamber occupies a process chamber area on the sample processing device, and the process chamber area has a length and a width transverse to the

length, and the length is greater than the width. The valved process chamber also includes a valve chamber located within the process chamber area, the valve chamber located between the process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the process chamber by a valve septum separating the valve chamber and the process chamber, and wherein a portion of the process chamber volume lies between the valve septum and the first major side of the sample processing device. At least a portion of the valve chamber is located within a valve lip extending into the process chamber area, and the valve septum is formed in the valve lip. The valved process chamber also includes a detection window located within the process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the process chamber volume. Exemplary embodiments of valved process chambers on sample processing devices according to claim 1 can be found in the application as filed at, e.g., page 6, lines 1-22; page 8, line 6 to page 9, line 30; and Figures 1-2 (where process chambers 40, valve chambers 60, valve lips 50, and valve septums 64 are described and depicted).

Appellants' invention, as recited in dependent claim 2, is directed to a valved process chamber according to claim 1, wherein the detection window is coextensive along the length of the process chamber with the valve septum. An exemplary embodiment of the features recited in claim 2 may be found in the application as filed at, e.g., page 11, lines 7-8 and Figure 3A (where detection windows 142 and valve septums 164 are depicted and described).

Appellants' invention, as recited in dependent claim 3, is directed to a valved process chamber according to claim 1, wherein the detection window is formed through the first major side of the sample processing device. An exemplary embodiment of the features recited in claim 3 may be found in the application as filed at, e.g., page 8, lines 6-32 and Figure 2 (where the first major side 15 is depicted and described).

Appellants' invention, as recited in dependent claim 4, is directed to a valved process chamber according to claim 1, wherein the detection window is formed through the second major side of the sample processing device. An exemplary embodiment of the features recited in claim 4 may be found in the application as filed at, e.g., page 8, lines 6-32 and Figure 2 (where second major side 19 is described and depicted).

Appellants' invention, as recited in dependent claim 5, is directed to a valved process chamber according to claim 1, wherein the valve chamber and the detection window occupy mutually exclusive portions of the process chamber area. An exemplary embodiment of the features recited in claim 5 may be found in the application as filed at, e.g., page 10, lines 12-17 and Figure 3A (where valve chambers 160 and detection windows 142 are described and depicted).

Appellants' invention, as recited in dependent claim 6, is directed to a valved process chamber according to claim 1, wherein the detection window is formed through the second major side of the sample processing device, and wherein the valve chamber and the detection window occupy mutually exclusive portions of the process chamber area. An exemplary embodiment of the features recited in claim 6 may be found in the application as filed at, e.g., page 8, lines 31-32; page 10, lines 12-17, and Figures 2 and 3A ((where valve chambers 160 and detection windows 142 are described and depicted).

Appellants' invention, as recited in dependent claim 7, is directed to a valved process chamber according to claim 1, wherein the valve septum extends along the length of the process chamber area for 30% or more of a maximum length of the process chamber area. An exemplary embodiment of the features recited in claim 7 may be found in the application as filed at, e.g., page 11, lines 14-17, and Figure 3A (where process chambers 140 and valve septums 142 are described and depicted).

Appellants' invention, as recited in dependent claim 8, is directed to a valved process chamber according to claim 1, wherein the valve septum extends for a length of 1 millimeter or more along the length of the process chamber. An exemplary embodiment of the features recited in claim 8 may be found in the application as filed at, e.g., page 11, lines 17-20 and Figure 3A (where process chambers 140 and valve septums 142 are described and depicted).

Appellants' invention, as recited in dependent claim 9, is directed to a valved process chamber according to claim 1, wherein the sample processing device is opaque between the process chamber volume and the first major side of the sample processing device. An exemplary embodiment of the features recited in claim 9 may be described in the application as filed at, e.g., page 9, lines 8-13 and Figure 2.

Appellants' invention, as recited in dependent claim 11, is directed to a valved process chamber according to claim 1, wherein the valve lip occupies only a portion of the width of the process chamber area. An exemplary embodiment of the features recited in claim 11 may be described in the application as filed at, e.g., page 15, lines 9-13 and Figure 4 (where process chambers 240 and valve lips 250a & 250b are described and depicted).

Appellants' invention, as recited in dependent claim 12, is directed to a valved process chamber according to claim 11, wherein the detection window occupies at least a portion of the width of the process chamber area that is not occupied by the valve lip. An exemplary embodiment of the features recited in claim 12 may be described in the application as filed at, e.g., page 14, lines 6-12 and Figure 4 (where detection windows 242 and valve lips 250a, 250b, & 250c are described and depicted).

Appellants' invention, as recited in independent claim 13, is directed to a valved process chamber on a sample processing device, the valved process chamber including a process chamber having a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the process chamber occupies a process chamber area on the

sample processing device. The process chamber area has a length and a width transverse to the length, and the length is greater than the width. The valved process chamber also includes a detection window located within the process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the process chamber volume. A valve chamber is located within the process chamber area, the valve chamber located between the process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the process chamber by a valve septum separating the valve chamber and the process chamber. A portion of the process chamber volume lies between the valve septum and a first major side of the sample processing device. The valve chamber and the detection window occupy mutually exclusive portions of the process chamber area. At least a portion of the valve chamber is located within a valve lip extending into the process chamber area, and the valve septum is formed in the valve lip. Exemplary embodiments of valved process chambers on sample processing devices according to claim 13 can be found in the application as filed at, e.g., page 6, lines 1-22; page 8, line 6 to page 11, line 6; and Figures 1, 2, and 3A (where process chambers 40/140, valve chambers 60/160, valve lips 50/150, and valve septums 64/164 are described and depicted).

Appellants' invention, as recited in independent claim 14, is directed to a method of selectively removing sample material from a process chamber. The method includes providing a sample processing device that includes a process chamber having a process chamber volume. The process chamber occupies a process chamber area on the sample processing device. The process chamber area has a length and a width transverse to the length, and the length is greater than the width. Also included is a valve chamber located within the process chamber area. The valve chamber is isolated from the process chamber by a valve septum located between the valve chamber and the process chamber. A detection window is located within the process chamber area, wherein the detection window is transmissive for selected electromagnetic energy. The

method also includes providing sample material in the process chamber and detecting a characteristic of the sample material in the process chamber through the detection window. The method further includes forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material; and moving only a portion of the sample material from the process chamber into the valve chamber through the opening formed in the valve septum. Exemplary methods according to claim 14 are described in the application as filed at, e.g., page 9, line 31 to page 13, line 30 and in Figures 3A-3D (where process chambers 140, detection windows 142, valve chambers 160, valve septums 164, and sample materials 180 and their use are described and depicted).

Appellants' invention, as recited in dependent claim 15, is directed to a method according to claim 14, wherein moving only a portion of the sample material from the process chamber into the valve chamber comprises rotating the sample processing device. An exemplary method as recited in claim 15 may be described in the application as filed at, e.g., page 13, lines 14-30 and Figures 3C-3D.

Appellants' invention, as recited in dependent claim 16, is directed to a method according to claim 14, wherein the process chamber area has a length and a width transverse to the length, and further wherein the length is greater than the width. An exemplary method as recited in claim 16 may be described in the application as filed at, e.g., page 10, line 31 to page 11, line 6 and Figure 3A.

Appellants' invention, as recited in dependent claim 17, is directed to a method according to claim 14, wherein the detected characteristic comprises a free surface of the sample material, and wherein the portion of the sample material moved from the process chamber into the valve chamber comprises a selected volume of the sample material. An exemplary method as recited

in claim 17 may be described in the application as filed at, e.g., page 13, lines 8-30 and Figures 3C-3D.

Appellants' invention, as recited in dependent claim 18, is directed to a method according to claim 14, further comprising rotating the sample processing device to separate components of the sample material in the process chamber. An exemplary method as recited in claim 18 may be described in the application as filed at, e.g., page 12, lines 27-30 and Figures 3B-3C.

Appellants' invention, as recited in dependent claim 19, is directed to a method according to claim 18, wherein the detected characteristic of the sample material comprises a boundary between the separated components of the sample material, and wherein the portion of the sample material moved from the process chamber into the valve chamber comprises a portion of a selected component of the sample material. An exemplary method as recited in claim 19 may be described in the application as filed at, e.g., page 13, lines 4-30 and Figures 3C-3D.

Appellants' invention, as recited in dependent claim 20, is directed to a method according to claim 14, wherein moving only a portion of the sample material from the process chamber into the valve chamber comprises moving a selected volume of the sample material from the process chamber into the valve chamber. An exemplary method as recited in claim 20 may be described in the application as filed at, e.g., page 14, line 24 to page 15, line 8 and Figure 4.

Appellants' invention, as recited in dependent claim 21, is directed to a method according to claim 14, wherein the sample material comprises blood. An exemplary method as recited in claim 21 may be described in the application as filed at, e.g., page 11, lines 21-24 and Figure 3B.

Appellants' invention, as recited in independent claim 22, is directed to a method of selectively removing sample material from a process chamber. The method includes providing a sample processing device that includes a process chamber having a process chamber volume. The process chamber occupies a process chamber area on the sample processing device, wherein the process chamber area has a length and a width transverse to the length, and wherein the

length is greater than the width. A valve chamber is located within the process chamber area, wherein the valve chamber is isolated from the process chamber by a valve septum located between the valve chamber and the process chamber. A detection window is also located within the process chamber area, wherein the detection window is transmissive for selected electromagnetic energy. The method further includes providing sample material in the process chamber; detecting a characteristic of the sample material in the process chamber through the detection window; and forming an opening in the valve septum at a selected location within the process chamber area, wherein the selected location is correlated to the detected characteristic of the sample material. The method also includes moving only a portion of the sample material from the process chamber into the valve chamber through the opening formed in the valve septum by rotating the sample processing device. Exemplary methods according to claim 22 are described in the application as filed at, e.g., page 9, line 31 to page 13, line 30 and in Figures 3A-3D (where process chambers 140, detection windows 142, valve chambers 160, valve septums 164, and sample materials 180 and their use are described and depicted).

Appellants' invention, as recited in claim 23, is directed to a sample processing device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays includes a first process chamber that has a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the first process chamber occupies a first process chamber area on the sample processing device, and wherein the first process chamber area has a length and a width transverse to the length, and further wherein the length is greater than the width. The process array also includes a valve chamber located within the first process chamber area, the valve chamber located between the first process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the first process chamber by a valve septum separating the valve chamber and the first process chamber, and wherein a portion of the first process chamber

volume lies between the valve septum and the first major side of the sample processing device. The process array also includes a detection window located within the first process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the first process chamber volume. A conduit in the process array is in fluid communication with the valve chamber. A second process chamber is in fluid communication with the valve chamber through the conduit; wherein an opening formed in the valve septum places the second process chamber in fluid communication with the first process chamber. Exemplary embodiments of sample processing devices according to claim 23 can be found in the application as filed at, e.g., page 6, lines 1-22; page 8, line 6 to page 11, line 6; and Figures 1, 2, and 3A. (where process arrays 20/120, process chambers 40/140, detection windows 142, valve chambers 60/160, valve septums 64/164, and sample materials 180 are described and depicted).

Appellants' invention, as recited in dependent claim 24, is directed to a sample processing device according to claim 23, wherein each process array of the plurality of process arrays comprises a loading chamber in fluid communication with the first process chamber. An exemplary embodiment of the features recited in claim 24 may be found in the application as filed at, e.g., page 6, lines 18-21 and Figure 1 (where loading chambers 30 are described and depicted).

Appellants' invention, as recited in dependent claim 25, is directed to a sample processing device according to claim 23, wherein each process array of the plurality of process arrays comprises a loading chamber in fluid communication with the first process chamber through a conduit. An exemplary embodiment of the features recited in claim 25 may be found in the application as filed at, e.g., page 6, lines 18-21 and Figure 1 (where loading chambers 30 and conduits 32 are described and depicted).

Appellants' invention, as recited in dependent claim 26, is directed to a sample processing device according to claim 23, wherein each process array of the plurality of process arrays

extends from proximate a center of the sample processing device towards a periphery of the sample processing device such that the first process chamber is located closer to the center than the second process chamber for each process array of the plurality of process arrays. An exemplary embodiment of the features recited in claim 26 may be found in the application as filed at, e.g., page 6, lines 7-14 and Figure 1 (where first process chambers 40 and second process chambers 70 are described and depicted).

Appellants' invention, as recited in dependent claim 27, is directed to a sample processing device according to claim 23, wherein, for each process array of the plurality of process arrays, at least a portion of the valve chamber is located within a valve lip extending into the first process chamber area, and wherein the valve septum is formed in the valve lip. An exemplary embodiment of the features recited in claim 27 may be found in the application as filed at, e.g., page 10, lines 3-8 and Figure 3A (where process chambers 140, valve lips 150, valve chambers 160, and valve septums 164 are described and depicted).

Appellants' invention, as recited in dependent claim 28, is directed to a sample processing device according to claim 27, wherein the valve lip occupies only a portion of the width of the first process chamber area. An exemplary embodiment of the features recited in claim 28 may be described in the application as filed at, e.g., page 15, lines 9-13 and Figure 4 (where process chambers 240 and valve lips 250a & 250b are described and depicted).

Appellants' invention, as recited in dependent claim 29, is directed to a sample processing device according to claim 28, wherein, for each process array of the plurality of process arrays, the detection window occupies at least a portion of the width of the first process chamber area that is not occupied by the valve lip. An exemplary embodiment of the features recited in claim 29 may be described in the application as filed at, e.g., page 14, lines 6-12 and Figure 4 (where detection windows 242 and valve lips 250a, 250b, & 250c are described and depicted).

Appellants' invention, as recited in dependent claim 30, is directed to a sample processing device according to claim 23, wherein, for each process array of the plurality of process arrays, the valve chamber and the detection window occupy mutually exclusive portions of the first process chamber area. An exemplary embodiment of the features recited in claim 30 may be found in the application as filed at, e.g., page 10, lines 12-17 and depicted in connection with Figure 3A (where process chambers 140, detection windows 142, and valve chambers 160 are described and depicted).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

Review is requested of the rejection of claims 1-9 and 11-30 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VII. ARGUMENT

Claims 1-9 and 11-30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Appellants respectfully request review and reversal of this rejection as discussed herein.

In support of the rejection the Examiner has asserted that, "[a]s to claims 1-30, the terms 'valved' and 'valve' are confusing, as the written specification and disclosure seems to describe a wall 64 in which an opening if (*sic*) formed by a laser, and not a valve." *Final Office Action*, p. 3 (July 17, 2006). As further support for this rejection, it is also asserted that "[t]he term "valve" is not consistent with its regular meaning. After all, valves are reusable, and the disclosed creation of an opening in the wall 64 is not. Valves include seats and valve members. Puncturing a hole in the side of a pool does not suggest a valve. It merely suggests a broken

liner." *Id.* Appellants respectfully submit that this reasoning is insufficient to support a rejection under § 112, second paragraph.

A. The rejection does not address the actual language used in claims 1-9 and 11-30.

At the outset, Applicants note that the terms "valved" and "valve" are addressed in connection with this rejection as if the terms were recited alone in the claims. That is not, however, the case. In fact, the terms "valved" and "valve" are used as adjectives to modify nouns. Claims 1-9 and 11-30 recite (in order of appearance) a "valved process chamber", "valve chamber", "valve septum", and "valve lip". In other words, the claims recite the terms "valve" or "valved" in the form of an adjective to describe a feature (e.g., process chamber, chamber, septum, or lip) that is a part of a fluid control structure. This distinction has not been addressed in either of the Office Actions and, Appellants submit, is but one reason for reversal of this rejection.

B. The proper standards for a rejection under 35 U.S.C. § 112, second paragraph have not been applied.

In addition to failing to address the actual language of the rejected claims, the proper standard for a rejection under 35 U.S.C. § 112, second paragraph, has not been applied. The proper standard to apply in assessing a claim under 35 U.S.C. § 112, second paragraph, is whether the claim as a whole "apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent." M.P.E.P. §2173.02, p. 2100-211 (8th Ed., Rev. 5, August 2006) (*citing Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000)). Furthermore, the claims are not to interpreted in a vacuum. Rather, definiteness under 35 U.S.C. § 112, second paragraph, must be

determined on whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

None of the reasoning presented by the Examiner in support of this rejection addresses why the claims would fail to serve the notice function of 35 U.S.C. §112, second paragraph to one of ordinary skill in the art. Nor does the reasoning discuss why one of ordinary skill in the art would not be able to discern the limits of the claims when the claims are read in light of the specification.

As support for the position that one of ordinary skill in the art would understand the limits of the claims when the claims are read in light of the specification, Appellants note that the specification is replete with references to the valve structures recited in the claims. Appellants respectfully direct the Board's attention to the following passages in the specification as examples of the portions of the specification that would inform the understanding of one of ordinary skill in the art as to the boundaries of the rejected claims: page 1, line 22 to page 2, line 19 and page 9, line 14 to page 15, line 13.

In place of reasoned analysis as to why one of ordinary skill in the art would not understand the limits of the claims when read in light of the specification, the Examiner offers only unsupported, unduly constrictive, and narrow definitions as to what constitutes a valve. For example, the assertions presented in support of this rejection are that "valves are reusable" and that "[v]alves include seats and valve members". No support is offered for these limited definitions of what can constitute a valve. Nor is any discussion provided as to why the claims do not "have a meaning discernible to one of ordinary skill in the art." *See, e.g., Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

Appellants have previously noted that at least one patent reference cited by the Examiner (in support of withdrawn rejections under 35 U.S.C. §§ 102 & 103) includes a complete section describing "sacrificial valves" that do not include seats or valve members. *See, U.S. Patent No. 6,063,589,* col. 32, line 13 to col. 34, line 6 (cited in an Information Disclosure Statement submitted on March 11, 2004). In response to Appellants' citation of this reference, the Examiner asserted that "the reference seems to acknowledge that there is a difference between a valve and a one-time use element." *Office Action*, p. 5, lines 6-7 (July 17, 2006) (attached). It is instructive to note that although U.S. Patent No. 6,063,589 itself describes the features as "valves", the Examiner describes them as a "one-time use element" – failing to acknowledge the interpretation that one of ordinary skill in the art would draw from the reference itself.

Furthermore, the assertion is not that the reference teaches that valves cannot be "one-time use elements." Rather, the Examiner indicates that "the reference seems to acknowledge that there is a difference between a valve and a one-time use element." *Id.* (emphasis added). In other words, the Examiner's response to the clear teachings of U.S. Patent No. 6,063,589 is that the patent reference might acknowledge a difference between a valve and a "one-time use element" – not that one of ordinary skill in the art would not understand the meaning of the term "valve" when used in connection with a one-time use element. Again, the proper standard for a rejection under § 112, second paragraph is not being applied.

As further support for this rejection that Examiner also asserts that "[p]uncturing a hole in the side of a pool does not suggest a valve. It merely suggests a broken liner." Appellants respectfully submit that this assertion is also insufficient to support a proper § 112, second paragraph rejection. The assertion also fails to provide support for the rejection because (like the other assertions offered in support of this rejection) it does not address how or why one of ordinary skill in the art would not understand the boundaries of the rejected claims as would be required for a proper rejection under § 112, second paragraph.

In view of the above, Appellants respectfully submit that a proper rejection of claims 1-9 and 11-30 under 35 U.S.C. § 112, second paragraph has not been established. Review and reversal of the rejection of claims 1-9 and 11-30 by the Board are, therefore, respectfully requested.

VIII. SUMMARY

For the foregoing reasons, Appellant respectfully requests that the Board review and reverse the rejections of claims 1-9 and 11-30 as discussed herein and that notification of the allowance of these claims be issued.

Respectfully submitted by

Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
(612)305-1220

16 JAN. 2007
Date

By: 
Kevin W. Raasch
Reg. No. 35,651
Direct Dial: (612) 305-1218

CLAIMS APPENDIX

Serial No.: 10/734,717

Docket No.: 59071US002

Claims 1-9 and 11-30 are provided below.

1. A valved process chamber on a sample processing device, the valved process chamber comprising:

a process chamber comprising a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the process chamber occupies a process chamber area on the sample processing device, and wherein the process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width;

a valve chamber located within the process chamber area, the valve chamber located between the process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the process chamber by a valve septum separating the valve chamber and the process chamber, and wherein a portion of the process chamber volume lies between the valve septum and the first major side of the sample processing device;

wherein at least a portion of the valve chamber is located within a valve lip extending into the process chamber area, and wherein the valve septum is formed in the valve lip; and

a detection window located within the process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the process chamber volume.

2. A valved process chamber according to claim 1, wherein the detection window is coextensive along the length of the process chamber with the valve septum.

3. A valved process chamber according to claim 1, wherein the detection window is formed through the first major side of the sample processing device.

4. A valved process chamber according to claim 1, wherein the detection window is formed through the second major side of the sample processing device.

5. A valved process chamber according to claim 1, wherein the valve chamber and the detection window occupy mutually exclusive portions of the process chamber area.

6. A valved process chamber according to claim 1, wherein the detection window is formed through the second major side of the sample processing device, and wherein the valve chamber and the detection window occupy mutually exclusive portions of the process chamber area.

7. A valved process chamber according to claim 1, wherein the valve septum extends along the length of the process chamber area for 30% or more of a maximum length of the process chamber area.

8. A valved process chamber according to claim 1, wherein the valve septum extends for a length of 1 millimeter or more along the length of the process chamber.

9. A valved process chamber according to claim 1, wherein the sample processing device is opaque between the process chamber volume and the first major side of the sample processing device.

11. A valved process chamber according to claim 1, wherein the valve lip occupies only a portion of the width of the process chamber area.

12. A valved process chamber according to claim 11, wherein the detection window occupies at least a portion of the width of the process chamber area that is not occupied by the valve lip.

13. A valved process chamber on a sample processing device, the valved process chamber comprising:

a process chamber comprising a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the process chamber occupies a process chamber area on the sample processing device, and wherein the process chamber area

comprises a length and a width transverse to the length, and further wherein the length is greater than the width;

a detection window located within the process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the process chamber volume; and

a valve chamber located within the process chamber area, the valve chamber located between the process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the process chamber by a valve septum separating the valve chamber and the process chamber, and wherein a portion of the process chamber volume lies between the valve septum and a first major side of the sample processing device, and further wherein the valve chamber and the detection window occupy mutually exclusive portions of the process chamber area, and still further wherein at least a portion of the valve chamber is located within a valve lip extending into the process chamber area, and wherein the valve septum is formed in the valve lip.

14. A method of selectively removing sample material from a process chamber, the method comprising:

providing a sample processing device comprising:

a process chamber comprising a process chamber volume, wherein the process chamber

occupies a process chamber area on the sample processing device, and wherein the process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width;

a valve chamber located within the process chamber area, wherein the valve chamber is isolated from the process chamber by a valve septum located between the valve chamber and the process chamber; and

a detection window located within the process chamber area, wherein the detection window is transmissive for selected electromagnetic energy;

providing sample material in the process chamber;

detecting a characteristic of the sample material in the process chamber through the detection window;

forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material; and

moving only a portion of the sample material from the process chamber into the valve chamber through the opening formed in the valve septum.

15. A method according to claim 14, wherein moving only a portion of the sample material from the process chamber into the valve chamber comprises rotating the sample processing device.

16. A method according to claim 14, wherein the process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width.

17. A method according to claim 14, wherein the detected characteristic comprises a free surface of the sample material, and wherein the portion of the sample material moved from the process chamber into the valve chamber comprises a selected volume of the sample material.

18. A method according to claim 14, further comprising rotating the sample processing device to separate components of the sample material in the process chamber.

19. A method according to claim 18, wherein the detected characteristic of the sample material comprises a boundary between the separated components of the sample material, and wherein the portion of the sample material moved from the process chamber into the valve chamber comprises a portion of a selected component of the sample material.

20. A method according to claim 14, wherein moving only a portion of the sample material from the process chamber into the valve chamber comprises moving a selected volume of the sample material from the process chamber into the valve chamber.

21. A method according to claim 14, wherein the sample material comprises blood.

22. A method of selectively removing sample material from a process chamber, the method comprising:

providing a sample processing device comprising:

a process chamber comprising a process chamber volume, wherein the process chamber occupies a process chamber area on the sample processing device, and wherein the process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width;

a valve chamber located within the process chamber area, wherein the valve chamber is isolated from the process chamber by a valve septum located between the valve chamber and the process chamber; and

a detection window located within the process chamber area, wherein the detection window is transmissive for selected electromagnetic energy;

providing sample material in the process chamber;

detecting a characteristic of the sample material in the process chamber through the detection window;

forming an opening in the valve septum at a selected location within the process chamber area, wherein the selected location is correlated to the detected characteristic of the sample material; and

moving only a portion of the sample material from the process chamber into the valve chamber through the opening formed in the valve septum by rotating the sample processing device.

23. A sample processing device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a first process chamber that comprises a process chamber volume located between opposing first and second major sides of the sample processing device, wherein the first process chamber occupies a first process chamber area on the sample processing device, and wherein the first process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width;

a valve chamber located within the first process chamber area, the valve chamber located between the first process chamber volume and the second major side of the sample processing device, wherein the valve chamber is isolated from the first process chamber by a valve septum

separating the valve chamber and the first process chamber, and wherein a portion of the first process chamber volume lies between the valve septum and the first major side of the sample processing device;

a detection window located within the first process chamber area, wherein the detection window is transmissive to selected electromagnetic energy directed into and/or out of the first process chamber volume;

a conduit in fluid communication with the valve chamber; and

a second process chamber in fluid communication with the valve chamber through the conduit; wherein an opening formed in the valve septum places the second process chamber in fluid communication with the first process chamber.

24. A sample processing device according to claim 23, wherein each process array of the plurality of process arrays comprises a loading chamber in fluid communication with first process chamber.

25. A sample processing device according to claim 23, wherein each process array of the plurality of process arrays comprises a loading chamber in fluid communication with first process chamber through a conduit.

26. A sample processing device according to claim 23, wherein each process array of the plurality of process arrays extends from proximate a center of the sample processing device towards a periphery of the sample processing device such that the first process chamber is located closer to the center than the second process chamber for each process array of the plurality of process arrays.

27. A sample processing device according to claim 23, wherein, for each process array of the plurality of process arrays, at least a portion of the valve chamber is located within a valve lip extending into the first process chamber area, and wherein the valve septum is formed in the valve lip.

28. A sample processing device according to claim 27, wherein the valve lip occupies only a portion of the width of the first process chamber area.

29. A sample processing device according to claim 28, wherein, for each process array of the plurality of process arrays, the detection window occupies at least a portion of the width of the first process chamber area that is not occupied by the valve lip.

30. A sample processing device according to claim 23, wherein, for each process array of the plurality of process arrays, the valve chamber and the detection window occupy mutually exclusive portions of the first process chamber area.

EVIDENCE APPENDIX

Serial No.: 10/734,717

Docket No.: 59071US002

---

1. Advisory Action mailed on November 6, 2006.
2. U.S. Patent No. 6,063,589 to Kellogg et al. (entered into the record by citation in an Information Disclosure Statement filed on March 11, 2004).
3. PTO Form 1449 returned to Appellants with Office Action mailed on August 10, 2005 indicating consideration of U.S. Patent No. 6,063,589 to Kellogg et al. on June 17, 2004.

UNITED STATES PAT. AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,717	12/12/2003	William Bedingham	59071US002	2357

32692 7590 11/06/2006

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
RAEVIS, ROBERT R	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)
10/734,717	BEDINGHAM ET AL.
Examiner	**Art Unit**
Robert R. Raevis	2856

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): All art rejections, and 112(2) that related only to claim 23.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *1-9 and 11-30*.
   Claim(s) rejected: *1-9,11-30 under 112(2) due to the term "valve"*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

RAEVIS
AU2856

Continuation of 11. does NOT place the application in condition for allowance because: As to the outstanding 112(2), whether noun or modifier, the Undersiged has serious difficulties with a claim that calls for valve functions/features when there is no valve..

Continuation of 13. Other: As to Claim 14, note was made of "the selected location is correlated" (line 4 from last) with remaining claim limitations; and as to Claim 23, note was made of a "plurality" (line 1) of particularly claimed arrays, each having a proces chamber "between opposing first and second major sides of the sampling proces device".

INFORMATION DISCLOSURE STATEMENT	Atty. Docket No.: 59071US002	Serial No.: 10/734,717
	Applicant(s): BEDINGHAM et al.	Confirmation No.:
	Application Filing Date: 12 December 2003	Group: Unassigned
	Information Disclosure Statement mailed: March 11, 2004	

U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
RL		6,063,589	05/16/00	Kellogg et al.			
RL		6,143,247	11/07/00	Sheppard, Jr. et al.			
RL		6,143,248	11/07/00	Kellogg et al.			
RL		6,302,134 B1	10/16/01	Kellogg et al.			
RL		6,632,399 B1	10/14/03	Kellogg et al.			
RL		6,527,432 B2	03/04/03	Kellogg et al.			
RL		6,548,788 B2	04/15/03	~~Kellogg et al.~~ Takahashi			
RL		6,582,662 B1	06/24/03	Kellogg et al.			
RL		6,627,159 B1	09/30/03	Bedingham et al.			
RL		6,632,399 B1	10/14/03	Kellogg et al.			
RL		2002/0047003 A1	04/25/02	Bedingham et al.			
RL		2002/0048533 A1	04/25/02	Harms et al.			
RL		2002/0064885 A1	05/30/02	Bedingham et al.			
RL		2003/0044322 A1	03/06/03	Andersson et al.			
RL		2003/0053934 A1	03/20/03	Andersson et al.			
RL		2003/0138779 A1	07/24/03	Parthasarathy et al.			
RL		2003/0152491 A1	08/14/03	Kellogg et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
		~~NONE~~						

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
		NONE

EXAMINER	Date Considered
RAEVIS	6-17-04

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RELATED PROCEEDINGS APPENDIX

Serial No.: 10/734,717

Docket No.: 59071US002

There are no appeals or interferences known to Appellant's Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

CITED AUTHORITIES AND DOCUMENTS

Serial No.: 10/734,717

Docket No.: 59071US002

---

1. M.P.E.P. §2173.02, p. 2100-211 (8th Ed., Rev. 5, August 2006).
2. *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000).
3. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).
4. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings,* 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). >But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); *Ex parte Huber*, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.).<

2173 Claims Must Particularly Point Out and Distinctly Claim the Invention

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

2173.01 Claim Terminology [R-2]

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01.< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

2173.02 Clarity and Precision [R-3]

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283

(Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 paragraph 2.). >See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.").

Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence").<

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites "a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc." The mere use of the phrase "such as" in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms "suitable liquid" and "solids of a filtering agent" in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. If upon review of the claim as a whole in light of the specification, the examiner determines that a rejection under 35 U.S.C. 112, second paragraph, is not appropriate in the above-noted example, but is of the opinion that the clarity and the precision of the language can be improved by the deletion of the phrase "such as" in the claim, the examiner may make such a suggestion to the applicant. If applicant does not accept the examiner's suggestion, the examiner should not pursue the issue.

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office action. If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicant's arguments to be persuasive, the examiner should indicate in the next Office communication that the previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner's position (e.g., examiners may make specific reference to portions of applicant's remarks that were considered to be the basis as to why the previous rejection was withdrawn).

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important in that "[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process." In *Festo*, the court held that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." With respect to amendments made to comply with the requirements of 35 U.S.C. 112, the court stated that "[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply." *Id.*, at 1840, 62 USPQ2d at 1712. The court further stated that "when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language...the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Id.*, at 1842, 62 USPQ2d at 1713. Thus, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. 112, second paragraph.

2173.03 Inconsistency Between Claim *>and< Specification Disclosure or Prior Art [R-1] [R-1]

Although the terms of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. *In re Cohn*, 438 F.2d 989, 169 USPQ 95 (CCPA 1971); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). In *Cohn*, the claim was directed to a process of treating a surface with a corroding solution until the metallic appearance is supplanted by an "opaque" appearance. Noting that no claim may be read apart from and independent of the supporting disclosure on which it is based, the court found that the description, definitions and examples set forth in the specification relating to the appearance of the surface after treatment were inherently inconsistent and rendered the claim indefinite.

2173.04 Breadth Is Not Indefiniteness

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad. If the claim is too broad because it does not set forth that which applicants regard as their invention as evidenced by statements outside of the application as filed, a rejection under 35 U.S.C. 112, second paragraph, would be appropriate. If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph, would be appropriate. If the claim is too broad because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.

2173.05 Specific Topics Related to Issues Under 35 U.S.C. 112, Second Paragraph [R-1]

The following sections are devoted to a discussion of specific topics where issues under 35 U.S.C. 112, second paragraph, have been addressed. These sections are not intended to be an exhaustive list of the issues that can arise under 35 U.S.C. 112, second paragraph, but are intended to provide guidance in areas that have been addressed with some frequency in recent examination practice. The court and Board decisions cited are representative. As with all appellate decisions, the results are largely dictated by the facts in each case. The use of the same language in a different context may justify a different result.

>See MPEP § 2181 for guidance in determining whether an applicant has complied with

Intellectual Property Library
ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Solomon v. Kimberly-Clark Corp., 55 USPQ2d 1279 (Fed. Cir. 2000)

Solomon v. Kimberly-Clark Corp., 55 USPQ2d 1279 (Fed. Cir. 2000)

55 USPQ2d 1279
Solomon v. Kimberly-Clark Corp.
U.S. Court of Appeals Federal Circuit
No. 00-1033
Decided June 30, 2000
216 F3d 1372

Headnotes

PATENTS

[1] Patentability/Validity -- Specification -- Claim adequacy (▶ 115.1109)

Federal district court erred by comparing claims at issue with inventor's deposition testimony in holding claims invalid under second paragraph of 35 U.S.C. Section 112, since court, in evaluating claim under either "definiteness" or "which the applicant regards as his invention" portion of that paragraph, must limit its inquiry to way one of ordinary skill in art would interpret claims in view of written description portion of specification, since inventor testimony obtained in context of litigation is of little probative value in assessing validity under Section 112, second paragraph, especially in view of fact that determination of whether claim complies with that paragraph is drawn from court's performance of its duty as construer of claims, and since, once patent issues, claims and written description must be viewed objectively, from perspective of person of skill in art.

[2] Patentability/Validity -- Inventorship (▶ 115.13)

Infringement defendant failed to prove by clear and convincing evidence that asserted claims of patent in suit are invalid under 35 U.S.C. Section 102(f) for failure to name true inventor, since defendant relied entirely on inventor's lack of precision in defining her invention in course of deposition, rather than introducing evidence that someone else was true inventor, and since, despite some vagueness and inconsistency in her deposition testimony, inventor maintained throughout litigation that she invented claimed subject matter, and submitted evidence that prototype in her patent attorney's files embodied claimed invention.

Particular Patents

Particular patents -- General and mechanical -- Disposable underwear

4,560,381, Southwell, disposable panty for menstrual wear, summary judgment of invalidity *reversed*.

Case History and Disposition

Appeal from the U.S. District Court for the District of Arizona, Broomfield, C.J.

Action by Sandra Solomon against Kimberly-Clark Corp. for patent infringement. Plaintiff appeals from summary judgment of invalidity on ground of indefiniteness. Reversed.

Attorneys

Jeffrey L. Weiss and Harry M. Weiss, of Harry M. Weiss & Associates, Scottsdale, Ariz., for plaintiff-appellant.

William H. Baumgartner Jr., of Sidley & Austin, Chicago, Ill.; V. Bryan Medlock Jr., of Sidley & Austin, Dallas, Texas; Joseph S. Miller and Carter G. Phillips, of Sidley & Austin, Washington, D.C.; Harry M. Beggs, of Carson Messinger, Phoenix, Ariz., for defendant-appellee.

Judge

Before Lourie, Clevenger, and Bryson, circuit judges.

Opinion Text

Opinion By:

Lourie, J.

Sandra Solomon appeals from the decision of the United States District Court for the District of Arizona granting Kimberly- Clark Corporation's motion for summary judgment that the claims of U.S. Patent 4,560,381 are invalid as indefinite under 35 U.S.C. Section 112, Para. 2. *See Solomon v. Kimberly-Clark Corp.* , No. CIV 96-2000 PHX RCB (D. Ariz. Sept. 2, 1999) (" *Solomon II* "). Because the district court erred in holding the claims invalid under that provision of the statute, we reverse.

BACKGROUND

A. *The Claimed Invention*

Sandra Southwell (now Sandra Solomon) is the named inventor on the '381 patent,

Page 1280

which is directed to disposable panties and panty liners for use during a woman's menstrual cycle. Independent claim 1, which is representative of the claims at issue, reads as follows:

> 1. A disposable woman's protective menstrual panty for holding a feminine napkin comprising: a relatively thick layer of disposable absorbent material; and a depression means in said relatively thick layer of disposable absorbent material, said depression means including a substantially thinner layer of disposable absorbent material operably disposed longitudially [sic] in the crotch area of said panty and extending at least partially upward thereof in both front and rear areas, said depression means being dimensioned for receiving said feminine napkin therein for positioning same during use.

'381 patent, col. 17, l. 65 to col. 18, l. 9. Figures 1 and 2 of the '381 patent, which have been *modified* for clarity, depict the preferred embodiment of the claimed invention in the following manner:

As illustrated by the figures, panty 21 is divided into body portion 22, waist portion 23, crotch portion 24, and leg portions 25. *See id.* at col. 5, ll. 58-60. Body portion 22 is itself divided at division line 28 into

top portion 26 and bottom portion 27. *See id.* at col. 5, ll. 60-62. Top portion 26 is preferably made of lightweight open mesh-type material or fabric, and the outer surface of bottom portion 27 may be made of the same or different material, *e.g.* , a woven, hydrophobic material. *See id.* at col. 5, l. 62 to col. 6, l. 27. The inner surface of bottom portion 27, however, is composed of a highly absorbent, thick layer 51. *See id.* at col. 6, ll. 37-43. Crotch portion 24 of lower portion 27 contains an elongated, oval-shaped depression 43 that is bounded on both sides by thick layer 51 (specifically labeled 44 in the crotch region) and contains a relatively thin layer of absorbent material at its base. *See id.* at col. 7, ll. 40-65. The depression functions to receive and to hold a commercially available feminine napkin or pad. *See id.* at col. 8, ll. 48-60.

B. *Procedural History*

Solomon sued Kimberly-Clark, alleging that its Personals(Registered) panty infringed all fifty- nine claims of the '381 patent. [1]The district court granted Kimberly-Clark's motion for summary judgment of noninfringement, holding that the Personals(Registered) panty did not infringe the claims of the patent either literally or under the doctrine of equivalents. On appeal, we upheld the district court's claim construction, as well as its conclusion that there was no genuine issue of material fact that the accused panties did not literally infringe. *See Solomon v. Kimberly-Clark Corp.* , No. 97-1571, 1998 WL 279346, at *2-*5 (Fed.Cir. May 26, 1998) (" *Solomon I* "). However, we vacated the judgment and *remanded* for further proceedings in view of our conclusion that genuine issues of material fact existed regarding infringement under the doctrine of equivalents. *See id.* at *4-*7.

---

[1] Because the details of Kimberly-Clark's product are not relevant to the issues presented on appeal, we do not discuss them here.

On remand, Kimberly-Clark again moved for summary judgment, alleging that the patent was invalid under 35 U.S.C.

Page 1281

Section 102(f) [2]because Solomon was not the true inventor of the claimed invention, or alternatively under 35 U.S.C. 112, Para. 2, [3]because Solomon failed to claim the subject matter that she regarded as her invention. *See Solomon II* , slip op. at 4. Kimberly-Clark based its allegations in part on Solomon's deposition testimony, in which she allegedly stated on several occasions that the depression limitation in the claimed invention was made of material having a uniform, rather than varying, thickness. *See id.* at 3. Kimberly-Clark contended that those statements were contrary to what was claimed in the patent, apparently based on our (and the district court's) construction of "depression" to mean a portion of the panty "formed by surrounding a region of substantially thinner material with a region of thicker material." *Solomon I* , 1998 WL 279346, at *2. Kimberly-Clark also based its arguments on Solomon's DX13 prototype of the claimed invention, which depicts an area of uniform thickness in the region where the depression is located. *See Solomon II* , slip op. at 3-4.

---

[2] Section 102(f) provides that:

A person shall be entitled to a patent unless--

* * * (f) he did not himself invent the subject matter sought to be patented . . . .

U.S.C. Section 102(f) (1994).

[3] Section 112, Para. 2, provides that:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
>
> U.S.C. Section 112, Para. 2 (1994).

The district court held that Kimberly- Clark had not proven that the claims of the patent were invalid under section 102(f), because Kimberly-Clark failed to name the "true inventor" on the patent. *See id.* at 9-10. The court reasoned that even if it were legally correct to invalidate patent claims under section 102(f) in the absence of proof of the identity of the true inventor, Kimberly-Clark had nonetheless failed to prove by clear and convincing evidence that Solomon was not the true inventor. *See id.* The district court concluded, however, that Solomon's deposition testimony revealed that "her patent does not accurately depict her invention" and thus held that there was no genuine issue of material fact that the patent was invalid under section 112, paragraph 2, for failure to claim "the subject matter which the applicant regards as his invention." *Id.* at 13-14. While acknowledging that this case did not involve a "typical" validity challenge under section 112, paragraph 2, the district court noted that it could "see little reason to ignore the mandate of Section 112 in such a case." *Id.* at 14. The court also held that Solomon's affidavit attesting to her inventorship was insufficient to prevent summary judgment on that issue. *See id.* at 14-16.

Solomon appealed the district court's invalidity ruling to this court. We have jurisdiction pursuant to 28 U.S.C. Section 1295(a)(1) (1994).

DISCUSSION

A. *Standard of Review*

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.* , 477 U.S. 242, 255 (1986). We review the grant of a motion for summary judgment *de novo* , reapplying the summary judgment standard. *See Kemco Sales, Inc. v. Control Papers Co.* , 208 F.3d 1352, 1359, 54 USPQ2d 1308, 1312 (Fed.Cir. 2000).

The determination whether a claim recites "the subject matter which the applicant regards as his invention," like a determination whether a claim is sufficiently definite, "is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *See Personalized Media Communications, LLC v. ITC* , 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed.Cir. 1998) (setting forth this reasoning in the context of definiteness). Thus, as with claim construction, a determination under either portion of section 112, paragraph 2, is a question of law that we review *de novo* . *See Atmel Corp. v. Information Storage Devices, Inc.* , 198 F.3d 1374, 1378, 53 USPQ2d 1225, 1227 (Fed.Cir. 1999) (setting forth this standard in the context of definiteness).

B. *Invalidity under Section 112, Paragraph 2*

Solomon argues that the district court erred in invalidating the claims of the '381 patent under section 112, paragraph 2, asserting that a court evaluates compliance with that provision by comparing the claims to the disclosure in the specification, not by

comparing the claims to an inventor's deposition testimony. Solomon alternatively contends that even if

the testimony and other evidence are considered, Kimberly-Clark has still failed to prove invalidity by clear and convincing evidence. Solomon also asserts that Kimberly-Clark's evidence and arguments really relate to inventorship, not definiteness, and such a challenge should have been raised under section 102(f). Kimberly-Clark responds that the language of section 112, paragraph 2, plainly states that patent claims must specify what "the applicant regards as his invention," and that therefore claims may be invalid if inventor testimony conflicts with the recitations of the claims. Kimberly-Clark further contends that based on the evidence it presented, it did succeed in proving that the claims of the '381 patent are invalid under section 112, paragraph 2.

[1] We agree with Solomon that the district court erred in invalidating the claims of the '381 patent under section 112, paragraph 2, based on Solomon's deposition testimony. As an initial matter, we note that for a claim to comply with section 112, paragraph 2, it must satisfy two requirements: first, it must set forth what "the applicant regards as his invention," and second, it must do so with sufficient particularity and distinctness, *i.e.* , the claim must be sufficiently "definite." *See* 35 U.S.C. Section 112, Para. 2; *see also* Irah H. Donner, *Patent Prosecution* ch. 9.VIII, at 933 (2d ed. 1999).

During the prosecution of a patent application, a claim's compliance with both portions of section 112, paragraph 2, may be analyzed by consideration of evidence beyond the patent specification, including an inventor's statements to the Patent and Trademark Office ("PTO"). *See In re Conley* , 490 F.2d 972, 976, 180 USPQ 454, 456-57 (CCPA 1974) (noting that the phrase "which the applicant regards as his invention" in the second portion of section 112, paragraph 2, "has been relied upon in cases where some material submitted by applicant, *other than his specification* , shows that a claim does not correspond in scope with what *he regards* as his invention."); *In re Moore* , 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (" [T]he definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.").

It is not inappropriate for the PTO or a reviewing tribunal to consider such evidence extrinsic to the patent application in light of the goals of the examination process and the fact that pending claims can be freely amended to comport with those goals. As we explained in *In re Zletz* :

> During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

In re Zletz , 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed.Cir. 1989) (citation omitted); *see In re Prater* , 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). Thus, in the more fluid environment of patent examination, an inventor's statements are relevant to determining compliance with the statute.

On the other hand, when a court analyzes whether *issued claims* comply with section 112, paragraph 2, the evidence considered in that analysis should be more limited. As for the "definiteness" portion of section 112, paragraph 2, our precedent is well-settled that a court will typically limit its inquiry to the way one of skill in the art would interpret the claims in view of the written description portion of the specification. As we stated in *Personalized Media* :

> Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more.

Personalized Media , 161 F.3d at 705, 48 USPQ2d at 1888 (internal quotation marks omitted); *see Atmel* , 198 F.3d at 1378, 53 USPQ2d at 1227-28 ("As a general matter, it is well-established that the determination whether a claim is invalid as indefinite depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification." (internal quotation marks omitted)). [4]Although

Page 1283

we have not specifically addressed the types of evidence that may be considered in analyzing whether a claim complies with the "which the applicant regards as his invention" portion of that statute, we see no reason for a different standard to apply, as the rationale for reviewing a limited range of evidence under either portion of the statute is the same.

---

[4] *See also* , *e.g.* , *Beachcombers v. Wildewood Creative Prods., Inc.* , 31 F.3d 1154, 1158, 31 USPQ2d 1653, 1656 (Fed.Cir. 1994); *North Am. Vaccine, Inc. v. American Cyanamid Co.* , 7 F.3d 1571, 1579, 28 USPQ2d 1333, 1339 (Fed.Cir. 1993); *Morton Int'l, Inc. v. Cardinal Chem. Co.* , 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1194-95 (Fed.Cir. 1993); *Miles Lab., Inc. v. Shandon Inc.* , 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed.Cir. 1993); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.* , 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed.Cir. 1986). Despite this general rule, in some circumstances evidence beyond the claims and written description may be reviewed. *See e.g.* , *Amgen, Inc. v. Chugai Pharm. Co.* , 927 F.2d 1200, 1217-18, 18 USPQ2d 1016, 1030-31 (Fed.Cir. 1991); *Texas Instruments Inc. v. ITC* , 871 F.2d 1054, 1063, 10 USPQ2d 1257, 1263-64 (Fed.Cir. 1989). Moreover, we note that the determination of the perspective of one of skill in the art may involve reference to evidence extrinsic to the patent, such as prior art and witness testimony. *See Orthoki - netics* , 806 F.2d at 1576, 1 USPQ2d at 1088 (referencing witness testimony); *see generally* 3 Donald S. Chisum, *Chisum on Patents* Section 7.03 [2] (2000) (discussing the "person skilled in the art" standard).

A more limited range of evidence should be considered in evaluating validity as opposed to patentability under either portion of section 112, paragraph 2, because the language of issued claims is generally fixed (subject to the limited possibilities of reissue and reexamination), the claims are no longer construed as broadly as is reasonably possible, and what the patentee subjectively intended his claims to mean is largely irrelevant to the claim's objective meaning and scope, *see Markman v. Westview Instruments, Inc.* , 52 F.3d 967, 985-86, 34 USPQ2d 1321, 1334-35 (Fed.Cir. 1995) (*en banc*), aff'd , 517 U.S. 370, 38 USPQ2d 1461 (1996). As has been noted in the context of definiteness, the inquiry under section 112, paragraph 2, now focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the patentee's right to exclude. *See United Carbon Co. v. Binney & Smith Co.* , 317 U.S. 228, 233, 55 USPQ 381, 384 (1942) ("To sustain claims so indefinite as not to give the notice required by the statute would be in direct contravention of the public interest which Congress therein recognized and sought to protect."); *see also* 3 Chisum, *supra* , Section 8.03, at 8-14. ("The primary purpose of this requirement of definiteness in claims is to provide clear warning to others as to what constitutes infringement of the patent.").

It is particularly inappropriate to consider inventor testimony obtained in the context of litigation in assessing validity under section 112, paragraph 2, in view of the absence of probative value of such testimony. In *Markman* , we addressed the closely related issue of litigation-derived inventor testimony in the context of claim construction, and concluded that such testimony is entitled to little, if any, probative value. *See Markman* , 52 F.3d at 985, 34 USPQ2d at 1332-33 (holding that inventor testimony as to " [t]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history)."); *see also Bell & Howell Document Management v. Altek Sys.* , 132 F.3d 701, 706, 45 USPQ2d 1033, 1038 (Fed.Cir. 1997) ("The testimony of an inventor and his attorney concerning claim construction is thus entitled to little or no consideration. The testimony of an inventor is often a self-serving, after-the-fact attempt to

state what should have been part of his or her patent application. . . ."); *Roton Barrier, Inc. v. Stanley Works* , 79 F.3d 1112, 1126, 37 USPQ2d 1816, 1826 (Fed.Cir. 1996) ("We have previously stated that an inventor's after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself.") (internal quotation marks omitted); *cf. Voice Techs. Group, Inc. v. VMC Sys., Inc* ., 164 F.3d 605, 615-16, 49 USPQ2d 1333, 1340-41 (Fed.Cir. 1999) (acknowledging that "the inventor can not by later testimony change the invention and the claims from their meaning at the time the patent was drafted and granted" but stating that the inventor may provide testimony explaining the claimed invention and its development). We reasoned that an inventor is not competent to construe patent claims for the following reasons:

> [C]ommonly the claims are drafted by the inventor's patent solicitor and they may even be drafted by the patent examiner in an examiner's amendment (subject to the approval of the inventor's solicitor). While presumably the inventor has approved any changes to the claim scope that have occurred via amendment during the prosecution process, it is not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO.

Markman , 52 F.3d at 985, 34 USPQ2d at 1335 (citation omitted). We find this analysis equally compelling in the present context, as the determination whether a claim complies with section 112, paragraph 2, is "drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media* , 161 F.3d at 705, 48 USPQ2d 1888 . Although we recognize that "which the applicant regards as his invention" is subjective language, *see* Donner, *supra* , ch. 9.VIII, at 933, once the patent issues, the claims and written description must be viewed objectively, from the standpoint of a person of skill in the art, *see Markman* , 52 F.3d at 986, 34 USPQ2d at 1335.

For the foregoing reasons, we conclude that inventor testimony, obtained in the context of litigation, should not be used to invalidate issued claims under section 112, paragraph 2. [5]Accordingly, we agree with Solomon that the district court erred in using her deposition testimony to invalidate the claims of the '381 patent under that provision of the statute. We have carefully considered Kimberly-Clark's remaining arguments, but find them unpersuasive.

---

[5] While Kimberly-Clark cites cases such as *Prater* , *Conley* , and *In re Cormany* , 476 F.2d 998, 177 USPQ 450 (CCPA 1973), for the proposition that inventor testimony obtained in the context of litigation can be used to invalidate a claim, as we have explained above, those cases address the use of inventor testimony in the context of *patent prosecution* . As for the district court cases cited by Kimberly-Clark, *see Bontrager v. Steury Corp.* , 457 F.Supp. 526, 201 USPQ 813 (N.D. Ind. 1978); *Inpro, Inc. v. A.W. Chesterton Co.* , 657 F.Supp. 935, 2 USPQ2d 1597 (N.D. Ill. 1987), they are not binding on us and are not persuasive.

C. *Invalidity under Section 102(f)*

Kimberly-Clark alternatively argues that the district court's judgment of invalidity should be *affirmed* because, contrary to that court's conclusion, the claims are also invalid under section 102(f); it asserts that someone other than Solomon must have conceived the invention claimed by the '381 patent. Kimberly-Clark contends that the claims require a depression formed from material having two different thicknesses, but the panty Solomon invented, as revealed by her deposition testimony and the DX13 prototype, did not contain such a depression. Kimberly-Clark notes that while Solomon argues that her approval of the patent application before it was filed and her oath of inventorship prove that she was the true inventor, her deposition testimony shows that she did not understand the application that her lawyer filed on her behalf. Lastly, while Kimberly-Clark acknowledges that it was unable to name the "true" inventor, it contends that section 102(f) only requires that the accused infringer prove by clear and

convincing evidence that the alleged patentee is not the true inventor, which it has done.

Solomon responds that the district court correctly held that the claims were not invalid under section 102(f). Solomon argues that Kimberly-Clark failed to prove invalidity by clear and convincing evidence, because Kimberly-Clark failed to prove the identity of the true inventor, and Solomon's allegedly inconsistent testimony was insufficient to invalidate the '381 patent. In any event, Solomon argues that she never testified that she was not the true inventor, and she notes that she actively assisted her patent attorney prepare her application and signed the oath of inventorship. While Solomon concedes that the DX13 prototype does in fact contain a depression region of uniform thickness, she points out that that prototype was one of several, and that another prototype, the DX2 prototype, contains a depression formed by material having two different thicknesses. Moreover, Solomon argues that her testimony and the prototypes are consistent with her contention from the beginning of this litigation that the patent claims cover both panties with a depression made of material having two different thicknesses and panties with a depression made of material of uniform thickness.

Section 102(f) provides that " [a] person shall be entitled to a patent unless--he did not himself invent the subject matter sought to be patented. . . ." 35 U.S.C. Section 102(f) (1994). Chisum explains that section 102(f)

> bars issuance of a valid patent to a person or persons who derive the conception of the invention from any other source or person. A corollary of this requirement is the rule of proper joinder of inventors. The rule operates both as to misjoinder (erroneous addition of a person who is not in fact a joint inventor) and as to nonjoinder (failure to add a joint inventor). Potentially, misjoinder and nonjoinder are as fatal to the validity of a patent (or the effectiveness of a filed application) as a case of complete inventorship error.

1 Chisum, *supra* , Section 2.03, at 2-40 & nn.1-2. If failure to comply with section 102(f) is proven by clear and convincing evidence, the claims of a patent will be held invalid. *See Pannu v. Iolab Corp.* , 155 F.3d 1344, 1349, 47 USPQ2d 1657, 1661 (Fed.Cir. 1998) (setting forth this standard in the context of nonjoinder). However, when a party has been misjoined or nonjoined, a patent may be saved from invalidity by operation of 35 U.S.C. Section 256. *See id.* at 1350, 47 USPQ2d at 1662.

[2] We agree with Solomon that the district court correctly held that Kimberly- Clark failed to prove by clear and convincing evidence that the claims of the '381 patent are invalid under section 102(f). Although we understand Kimberly-Clark to contend that the claims are invalid under section 102(f) either because Solomon is simply not the true inventor and thus should not be named on the patent, or that someone else (Kimberly-Clark suggests Solomon's patent attorney) invented the claimed invention and should have been joined but was not, both of Kimberly-Clark's assertions fail for the same reason: Kimberly-Clark relied entirely on Solomon's lack of precision in defining her invention in the course of her deposition and the DX13 prototype, rather than introducing clear and convincing evidence that someone else was the true inventor. While an inventor's statements made during the course of litigation might in some circumstances justify a court in concluding that the named inventor "did not himself invent the subject matter sought to be patented," 35 U.S.C. Section 102(f), it would require much stronger evidence that the named inventor was not the true inventor to justify a conclusion of clear and convincing evidence of invalidity. Despite some vagueness and inconsistency in Solomon's deposition testimony, she maintained throughout that she invented the claimed subject matter, and she submitted evidence that the DX2 prototype in her patent attorney's files embodied the claimed invention. Moreover, the DX13 prototype actually supports Solomon's position, as she has consistently maintained from the outset of the litigation that her invention includes panties and panty liners with a depression of uniform thickness. *See Solomon I* , 1998 WL 279346, at *2. In light of that evidence, and in light of the fact that Kimberly-Clark failed to offer any evidence that a different inventor was responsible for the invention, the district court was correct to deny Kimberly-Clark's motion for summary judgment of invalidity under section 102(f).

As for the suggestion that Solomon's attorney might be the true inventor, we regard that argument as misguided. An attorney's professional responsibility is to assist his or her client in defining her invention to

obtain, if possible, a valid patent with maximum coverage. An attorney performing that role should not be a competitor of the client, asserting inventorship as a result of representing his client. *Cf.* Patent and Trademark Office, U.S. Dep't of Commerce, *Manual of Patent Examining Procedure* app. R Section 10.64 (7th ed.1998) ("Avoiding acquisition of interest in litigation or proceeding before the [Patent and Trademark] Office"). Thus, to assert that proper performance of the attorney's role is a ground for invalidating the patent constitutes a failure to understand the proper role of a patent attorney. Accordingly, we conclude that the district court did not err in rejecting Kimberly-Clark's section 102(f) invalidity defense. We therefore need not assess the remaining evidence presented by Kimberly-Clark, or reach the parties' arguments relating to 35 U.S.C. Section 256.

CONCLUSION

The district court correctly concluded that Kimberly-Clark failed to prove that the claims of the '381 patent are invalid under section 102(f). However, the court erred in invalidating those claims under section 112, paragraph 2. We therefore *REVERSE* .

- End of Case -

Intellectual Property Library
ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Orthokinetics Inc. v. Safety Travel Chairs Inc., 1 USPQ2d 1081 (Fed. Cir. 1986)

Orthokinetics Inc. v. Safety Travel Chairs Inc., 1 USPQ2d 1081 (Fed. Cir. 1986)

1 USPQ2d 1081
Orthokinetics Inc. v. Safety Travel Chairs Inc.
U.S. Court of Appeals Federal Circuit
Nos. 85-2779 and 85-2812
Decided December 5, 1986
806 F2d 1565

Headnotes

PATENTS

[1] Patentability/Validity -- Anticipation -- Prior art (▶ 115.0703)

Patentability/Validity -- Anticipation -- Publication (▶ 115.0705)

Patentability/Validity -- Obviousness -- In general (▶ 115.0901)

Federal district court, in granting judgment notwithstanding verdict holding claims for wheelchair invalid as anticipated and obvious, erred by focusing on patent challenger's evidence regarding "on sale/public use" issue, rather than on evidence in support of jury's findings, erred by referring to jury's verdict as "ambiguous," since resolution of ambiguities is province of jury, erred by concluding that claimed invention was disclosed in publication, since claimed "head restraints" were not shown in that reference, and erred by employing inappropriate "would have been able to produce" test of obviousness.

[2] Patentability/Validity -- Construction of claims (▶ 115.03)

Federal district court, in granting judgment notwithstanding verdict holding claims for wheelchair invalid for indefiniteness under 35 USC 112, erred by requiring that one claim "describe" invention, since that is role of specification, and by applying "full, clear, concise, and exact" requirement of Section 112 to claim, since such section applies only to disclosure part of specification, and also erred by applying "able to produce" standard in place of statutory "obvious" standard of 35 USC 103.

[3] Infringement -- Contributory infringement (▶ 120.13)

Willful infringement is not prerequisite for imposition of personal liability upon corporate officers for their company's direct infringement.

Particular Patents

Particular patents -- Wheelchairs

3,815,586, Kazik, Orthopedic Chair With Scoliosis Pads, JNOV holding claims 5 and 6 invalid *reversed*.

Re. 30,867, Gaffney, Travel Chair, JNOV holding claims 1-5 invalid *reversed*.

Case History and Disposition

Appeal from District Court for the Northern District of Ohio, Aldrich, J.

Action by Orthokinetics Inc., against Safety Travel Chairs Inc., Entron Inc., William J. Pivacek, Clark Shipman, and William J. Cole, for patent infringement. From decision granting defendants' motions for JNOV and for new trial, both parties appeal. Reversed and *remanded* in part and *affirmed* in part.

Attorneys

Henry C. Fuller, and Fuller House & Hohenfeldt, S.C. both of Milwaukee, Wis. (Daniel J. Sammon, and Watts, Hoffmann, Fisher & Heinke Co., both of Cleveland, Ohio, on the brief) for appellant Orthokinetics Inc.

Charles B. Lyon, and Renner, Otto, Boissellee & Lyon, both of Cleveland, Ohio (Gordon D. Kinder, on the brief) for appellee Safety Travel Chairs Inc., et al.

Judge

Before Markey, Chief Judge, Newman, Circuit Judge, and Swygert, Senior Circuit Judge (for the Court of Appeals for the Seventh Circuit, sitting by designation).

Opinion Text

Opinion By:

Markey, Chief Judge.

Appeal and cross-appeal from a judgment of the United States District Court for the Northern District of Ohio, Civil Action No. C81-130. In Appeal No. 85-2779, Orthokinetics, Inc. (Orthokinetics) appeals from orders: (1) granting a judgment notwithstanding the verdict (JNOV) holding that: (a) claims 5 and 6 of its U.S. Patent No. 3,815,586 ('586 patent) are invalid under 35 U.S.C. § 102(b) and § 103; (b) claims 1-5 of its U.S. Patent Re. 30,867 ('867 patent) are invalid under 35 U.S.C. § 103 and § 112; (c) the defendant officers of defendant corporations are not personally liable for patent infringement and the corporations are free from charges of willful infringement; and (2) conditionally granting a new trial. We reverse and remand with instructions to reinstate the jury verdicts.

In Appeal No. 85-2812, the defendants (collectively, Safety) appeal from the judgment entered on the verdict on patent infringement and misuse, and denial of a new trial on those issues. We affirm.

BACKGROUND

I. *The Claimed Inventions*

Orthokinetics manufactures products for invalids and handicapped individuals, including pediatric wheelchairs. It is the assignee of the '586 patent issued to Raymond A. Kazik (Kazik) on June 11, 1974, entitled "Orthopedic Chair With Scoliosis Pads" and of the '867 patent reissued to Edward J. Gaffney (Gaffney) on February 16, 1982, entitled "Travel Chair".

The '586 patent discloses a wheelchair for treating persons, especially children, afflicted with scoliosis or curvature of the spine. The orthopedic wheelchair has a head restraint and a pair of laterally and vertically adjustable scoliosis pads attached at opposite sides of the chair and so positioned as to provide therapeutic contact with opposite sides of a person seated in the chair. The relevant claims read:

> 1. In a chair having a seat, a back, and means for supporting the same, the improvement comprising a pair of scoliosis pads each adapted to bear against the sides of a human body, and means for mounting said pads adjacent to opposite side of said chair in such position as to provide therapeutic contact with opposite sides of a person seated in said chair for treatment of curvature of the spine.
>
> 2. The improvement defined in claim 1 wherein said mounting means for each pad is vertically adjustable to permit said pads to be positioned in a vertically staggered relationship to develop a therapeutic force couple across said person's trunk tending to straighten out said curvature of the spine.
>
> 5. The improvement of claim 2 in combination with a head restraint which coacts with the scoliosis pads to exert therapeutic pressure on the spine.
>
> 6. The improvement of claim 5 in which said head restraint comprises pads which embrace the head and means for adjustably positioning said pads with respect to said back.

On January 26, 1981, Orthokinetics sued, alleging infringement of claims 5 and 6 of the nine claims in the '586 patent. On December 31, 1977, it had disclaimed claims 1 through 4. Because claims 5 and 6 depend from claims 1 and 2, however, they contain all of the limitations of claims 1 and 2.

The '867 reissue patent discloses a collapsible pediatric wheelchair which facilitates the placing of wheelchair-bound persons, particularly children, in and out of an automobile. Orthokinetics asserted infringement of claims 1 through 5 by Safety. Claim 1 reads (underscoring indicates language added by reissue]:

> 1. In a wheel chair having a seat portion, a front leg portion, and a rear wheel assembly, the improvement wherein said front leg portion is so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof whereby said front leg is placed in support relation to the automobile and will support the seat portion from the automobile in the course of subsequent movement of the wheel chair into the automobile and the *retractor* means for *assisting the attendant in* retracting said rear wheel assembly upwardly independently of any change in the position of the front leg portion with respect to the seat portion *while the front leg portion is supported on the automobile* and to a position which clears the space beneath the rear end of the chair and permits the chair seat portion retracted rear wheel assembly to be swung over and set upon said automobile seat.

Claim 2 eliminates the language added by reissue in claim 1 and adds:

> wherein said wheel chair has a chair frame including back portion extending upwardly from said seat portion and a front leg portion extending downwardly from said seat portion and wherein said rear wheel assembly includes a rear wheel frame that extends forwardly from said rear wheels and wherein said means for retracting said rear wheel assembly includes means pivotally connecting the front of said rear wheel frame to said chair frame, and a retractable strut connecting between said rear wheel assembly and said chair frame to support the wheel chair on the rear wheel assembly and to retract the rear wheel assembly upwardly under the chair seat portion by swinging said rear wheel frame upwardly.

Claim 3 limits the rear wheel frame of claim 2 to one which "comprises an upwardly arched undercarriage extending between said chair frame and rear wheels." Claim 4 limits the arch of the undercarriage of claim 3 to one which "substantially matches the angle between said seat portion and said front leg portion

whereby said undercarriage swings into close proximity to said leg portion and seat portion when said rear wheel assembly is retracted." Claim 5 limits the chair frame of claim 3 to one which "comprises spaced support tubes, said upwardly arched undercarriage fitting between said tubes when the undercarriage is retracted."

All five claims asserted are independent claims.

II. Procedural History

Orthokinetics introduced the Travel Chair to the market in November of 1973. In 1978, Safety Travel Chairs, Inc. (STC) began to sell similar chairs manufactured by Entron, Inc. (Entron). William J. Pivacek, Clark Chipman, and William J. Cole established STC and were the stockholders and officers of STC and Entron. When Orthokinetics sued STC, Entron, Pivacek, Chipman, and Cole, it alleged willful infringement of claims 5 and 6 of the '586 patent and various claims of its then U.S. Patent No. 3,891,229 ('229 patent). When the '229 patent reissued as the '867 patent on February 16, 1982, Orthokinetics amended its complaint to allege infringement of claims 1-5 of that patent, and demanded a jury trial. Safety answered that the patents were invalid and not infringed, and counterclaimed that Orthokinetics had misused its patents when it filed its complaint.

On the liability issues only, trial before a six-member jury was commenced on January 4, 1984, and continued until January 16. Unfortunately, the parties and the court did not decide, and apparently did not discuss, in a pretrial conference or otherwise before trial, just what the jury would be asked to do (*e.g* ., return a general verdict, a general verdict accompanied by answers to interrogatories, or a series of special verdicts on individual issues).

At the trial, the district court denied numerous motions for directed verdicts filed by the parties. Under Fed.R.Civ.P. 49 (the parties dispute whether under Rule 49(a) or (b)), the district court submitted to the jury a series of 54 jointly-prepared questions (samples of which are in the attached appendix). The questions recognized the appropriate burdens to be met by each of the parties as well as the corresponding standard of proof with respect to each issue. The jury returned its answers to the questions on anticipation, obviousness, infringement, willful infringement, misuse, and personal liability of the corporate officers. All were favorable to Orthokinetics.

Viewing the obvious/nonobvious conclusion as one that could be made only by the court, and therefore considering the jury's nonobvious verdict, *after* it was returned, to have been merely "advisory", the district court entered judgment on January 30, 1984 for Orthokinetics on the infringement and misuse issues only. On February 23, 1984, because it felt validity of the patents had not been decided, the district court denied Orthokinetics' motion for a temporary restraining order and preliminary injunction. On July 17, 1984, on becoming aware of this court's statement that "[t]he obviousness/nonobviousness issue is a legal issue and may be submitted to the jury with proper instructions," *Perkin-Elmer Corp. v. Computervision Corp* ., 732 F.2d 888, 894-95, 221 USPQ 669, 674 (Fed.Cir.), cert. denied , 469 U.S. 857 (1984), the district court entered judgment on the jury verdicts on patent validity and willful infringement.

Safety filed motions for JNOV on the issues of validity, infringement, and patent misuse, and in the alternative for a new trial.

III. *Summary of the District Court's Opinion*

On June 14, 1985, the district court filed a 69-page unpublished opinion, vacated its January 30 and July 17, 1984 judgments, and dismissed the complaint and counterclaim. It granted Safety's JNOV motion on validity, holding claims 5 and 6 of the '586 patent invalid because the claimed inventions were: (1) on sale or in public use, under § 102(b); and (2) described in a printed publication under § 102(b); and (3) obvious under § 103. The district court held claims 1-5 of the '867 patent invalid as: (1) indefinite under § 112; and

(2) drawn to inventions that could have been obvious under § 103.

The district court denied and granted portions of Safety's motion for JNOV on infringement. In its denial, it held STC and Entron guilty of infringement. In its grant, it held that (1) Chipman, Cole, and Pivacek had not infringed either of the two patents and were not personally liable for their corporation's infringement; and (2) no defendant had committed acts of willful infringement.

The district court denied Safety's motion for JNOV on patent misuse.

The district court conditionally granted Safety a new trial if this court were to reverse the district court's entry of JNOV holding the patents invalid. *See* Fed.R.Civ.P. 50(c)(1), 59(a).

On August 9, 1985, the district court amended its opinion in response to a motion filed by Safety.

ISSUES

(1) Whether the district court erred in granting Safety's motion for JNOV on validity of the '586 and '867 patents.

(2) Whether the district court erred in denying Safety's motion for JNOV on infringement.

(3) Whether the district court erred in granting Safety's motion on personal liability of corporate officers.

(4) Whether the district court erred in granting Safety's motion for JNOV on willful infringement.

(5) Whether the district court erred in denying Safety's motion for JNOV on patent misuse.

(6) Whether the district court abused its discretion in conditionally granting Safety a new trial.

(1) ***Safety's Motion for JNOV on Validity***

A. ***Introduction***

This appeal presents an uncommon and somewhat incongruous situation. The district court entered JNOV on validity in favor of the party who had the burden at trial to prove facts by clear and convincing evidence that would require a conclusion of obviousness. 35 U.S.C. § 282; *see, e.g., Connell v. Sears, Roebuck & Co* ., 722 F.2d 1542, 1550, 220 USPQ 193, 199-200 (Fed.Cir. 1983); *Moore v. Shultz* , 491 F.2d 294, 298-99, 180 USPQ 548, 551 (10th Cir.), cert. denied , 419 U.S. 930 [183 USPQ 385] (1974). Under the law set by Congress, a jury or a court may reach a conclusion that a patent remains valid *solely* on the failure of the patent challenger's evidence to convincingly establish the contrary. A patent being presumed valid at birth, § 282, a patentee need submit *no* evidence in support of a conclusion of validity by a court or a jury. If the patent challenger introduces evidence that might lead to a conclusion of invalidity, a patentee would be well advised to introduce evidence sufficient to rebut that of the challenger. If the challenger's evidence be totally inadequate, a patentee's motion for judgment or directed judgment that the challenger's § 282 burden had not been carried would be appropriately granted before the patentee introduces any rebuttal evidence.

This appeal also illustrates the confusion created in the field of patent litigation by the unwillingness of patentees and alleged infringers to proceed under the rules applicable to all other types of litigation in which a statute or case law has assigned burdens of proof. Courts can hardly be criticized for confusing the burden assignment when counsel proceed as though the statute, § 282, did not exist.

As here, patentees have historically sought to "go first" with testimony on validity, on the empirically unproven premise that a favorable "first impression" of the merits of the invention will carry through to victory. Courts and alleged infringers have acquiesced in the practice. The resulting erroneous but clear impression that patentees bear a burden of "proving validity" has frequently resulted in cluttered records, irrelevant detours, undue burdens on the judicial process, and unnecessary work for the trial court.

Recognizing that trials conducted in accord with the statutorily assigned burdens would not result in assured victory or more victories for either side, courts should consider pretrial orders designed to facilitate such trials.

Similarly, courts should consider pretrial orders in jury trials that specify precisely what the jury will be asked to do after it has been given instructions prepared in light of the evidence and at the end of its deliberations: (1) return a general verdict ("we find for plaintiff/defendant"); (2) return a general verdict accompanied by answers to factual interrogatories prepared in light of the evidence; (3) return special verdicts on specific issues appearing in the evidence ("we find for plaintiff/defendant on the XXXXXXX issue"; or (4) merely "advise." Unfortunately, as counsel stated at oral argument, that was not done here.

B. *Standard of Review*

This court has recently reiterated the standard under Fed.R.Civ.P. 5O(b) concerning a motion for JNOV in relation to an issue on which the movant did not have the burden of proof:

> A trial judge presented with a motion for JNOV (1) must consider all the evidence in a light most favorable to the nonmover, (2) must not determine credibility of witnesses, and (3) must not substitute his or her choice for the jury's in finding facts, drawing inferences, or deciding between conflicting elements in the evidence.

DMI, Inc. v. Deere & Co ., 802 F.2d 421, 425, 231 USPQ 276, 278 (Fed.Cir. 1986); *See Weinar v. Rollform Inc* ., 744 F.2d 797, 805, 223 USPQ 369, 373 (Fed.Cir. 1984), cert. denied , 105 S.Ct. 1844 (1985). If then the district court is "convinced upon the record before the jury that reasonable persons could not reach or could not have reached a verdict for the non-mover, it should grant the motion for directed verdict or for JNOV." *Connell* , 722 F.2d at 1546, 220 USPQ at 197; *see Quaker City Gear Works, Inc. v. Skil Corp* ., 747 F.2d 1446, 1454-55, 223 USPQ 1161 ,

(Fed.Cir. 1984), cert. denied , 105 S.Ct. 2676 (1985).

To convince this court that a trial judge erred in granting a motion for JNOV, an appellant need only show that there was substantial evidence to support the jury's findings and that those findings can support the jury's legal conclusion. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co* ., 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed.Cir.), cert. dismissed , 106 S.Ct. 340 (1985); *Railroad Dynamics, Inc. v. A. Stucki Co* ., 727 F.2d 1506, 1512, 220 USPQ 929, 936 (Fed.Cir.), cert. denied , 469 U.S. 871 (1984). " 'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp* ., 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed.Cir.), cert. denied , 469 U.S. 857 [225 USPQ 792].

Having carefully reviewed the record to determine whether there was such substantial evidence in support of each of the jury's critical findings, we are convinced that the district court inappropriately invaded the province of the jury, in derogation of Orthokinetics' rights as expressed in the Seventh Amendment to the Constitution.

C. *The '586 patent*

(*i) On Sale/Public Use, § 102(b*)

[1] The jury specifically found (question No. 31) that Safety failed to prove by clear and convincing evidence that the "subject matter" of claims 5 and 6 of the '586 patent was offered for sale or publicly used more than one year before its December 4, 1972 filing date. Because of that finding, the jury had no reason to, and did not answer the interrogatory on whether Orthokinetics had proved that what Safety alleged was a sale offer/public use was in fact done for an experimental purpose. The district court held that the jury's finding of no offer for sale or public use was "without basis in the record."

It was undisputed that Kazik and Gaffney took a prototype chair Kazik had built to several facilities including the Southern Colony Nursing Home in Wisconsin. On the basis of its view of Orthokinetics' answers to interrogatories and Kazik's trial testimony, the district court concluded that the chair taken to Southern Colony had all the elements of claims 5 and 6. The court stated that the "only testimony to the contrary, certain ambiguous remarks by Gaffney, contradict Orthokinetics' interrogatory answers." The court did not cite the record or otherwise identify the "remarks" referred to.

The district court then determined that the evidence "unmistakably reveals that the purpose of the trips to Southern Colony and other institutions was to commercialize the scoliosis pad chair," (though the jury made no finding on the purpose of the trips) and thus Orthokinetics was "not entitled to the 'experimental use' exception" (on which the jury also made no finding). Because there was insufficient evidence presented concerning the chairs brought to institutions other than Southern Colony, we mention those chairs no further.

The district court focused on evidence in support of Safety's contentions, rather than on evidence in support of the jury's findings. That approach constitutes reversible legal error, particularly where, as here, it involves a virtual disregard of substantial evidence on which the jury could reasonably have reached a contrary determination.

In referring to the evidence in support of the jury's verdict, the district court dismissed it as being "ambiguous". In that characterization, the district court lost sight of the rules, i.e., that resolution of ambiguities (assuming they existed) is a role assigned the jury, and inferences are to be drawn in favor of the nonmovant, Orthokinetics. Thus the court's dismissal of the evidence relied on by the jury as merely "ambiguous" was further legal error.

Orthokinetics points to substantial evidence showing that the Southern Colony chair lacked, among other things, a head restraint coacting with scoliosis pads with vertical adjustability, and that that chair's entire supporting structure and pad adjusting system was completely changed after the trip to Southern Colony. Alternatively, Orthokinetics challenges the district court's independent determination that it had not established that that chair was taken to Southern Colony for experimental purposes.

Focusing on its *own* evidence, Safety responds that "neither contention [of Orthokinetics] is supported by the evidence as a whole," thereby indicating a misunderstanding of our appellate role. If we were to determine what the "evidence as a whole" supports, there would be no need for trials or for Rule 50(b). Indeed, Safety's entire argument on appeal reflects its misunderstanding of the rules of Civil and Appellate Procedure governing a jury's role, a district court's role in reviewing motions for JNOV, and this court's role in reviewing that determination. Hence, acceptance of Safety's approach would not only violate established standards of review, but would render a jury impotent.

Safety concedes that the parties submitted evidence on both sides of each issue. Safety then attacks Orthokinetics' evidence, which is not at issue. As above indicated, Safety bore the burden under 35 U.S.C. § 282, and the jury had the right to reject *its* evidence as insufficient to carry that burden. Under those circumstances, this court may determine only whether the evidence the jury could have believed in making its critical findings was substantial. Because a jury must by definition be permitted to accept some

probative evidence and reject other probative evidence, we may not decide whether we would as jurors have found Orthokinetics' evidence, in Safety's words, "believable in light of the evidence as a whole." This is not a case in which there was no evidence in support of a jury's finding, or one in which the only evidence relating to a finding was contrary to that finding. *See Connell v. Sears, Roebuck & Co* ., 722 F.2d 1542, 1550, 220 USPQ 193, 200 (Fed.Cir. 1983) ("the jury finding that there was 'no prior art' could not possibly stand in the face of the numerous clearly relevant prior art patents in the trial record").

As too often occurs, the parties here have difficulty restricting themselves to the language of the claims. In distinguishing the Southern Colony chair, for example, Orthokinetics cites a structural feature, "shown" in the patent and a feature that was later *modified*; yet those features are not found as limitations in the claims.

There is, however, substantial evidence that the Southern Colony chair did not have the claimed elements "a head restraint which coacts with the scoliosis pads" or a "head restraint which comprises pads which embrace the head." It is clear that the jury could have so concluded on the evidence presented to it. Gaffney testified as to that difference, and the exhibits showing the Southern Colony chair fully support that testimony. Moreover, Kazik did not testify, and Orthokinetics' interrogatory answers did not state, that that chair had a head restraint coacting with the pads. Whether there may or may not have been evidence that might have supported a contrary conclusion is simply irrelevant. Because there was substantial evidence supporting it, the jury's determination that there was no offer for sale or public use of the *claimed* invention should not have been disturbed. The judgment NOV on the on sale or in public use bar must be vacated and judgement must be entered on the jury's verdict.

Because there was substantial evidence on which a reasonable jury could have found that Safety failed to prove an offer for sale or public use of the claimed invention, we need not discuss the district court's independent determination that Orthokinetics had not established an experimental purpose in the trip to Southern Colony. In light of the instructions given the jury, moreover, it must be concluded that any consideration it gave the question of experimental purpose was resolved by the jury in Orthokinetics' favor. Nonetheless, for the benefit of the parties, we note that Orthokinetics did come forward with evidence of an experimental purpose sufficient to have convinced the jury that even the possibility of a public use bar had been "negated". *TP Laboratories, Inc. v. Professional Positioners, Inc* ., 724 F.2d 965, 971, 220 USPQ 577, 582 (Fed.Cir.), cert. denied , 469 U.S. 826 [224 USPQ 616] (1984); *see also In re Smith* , 714 F.2d 1127, 218 USPQ 976 (Fed.Cir. 1983).

Gaffney testified at trial that the purpose of the trip to Southern Colony was to "test [the chair] with some handicapped children to see if it was ready" and "to see if the chair was ready to be commercialized and if it would do the job we wanted it to do." The jury had the right to construe that testimony as establishing that Orthokinetics was still in an experimental phase when the visit was made to Southern Colony. Whether Kazik's statement that the trip was to see "the scope of the market" might support a contrary conclusion is of no moment in the course of considering a motion for JNOV. The district court's characterization of Kazik's and Gaffney's testimony as "undisputed" is but an indication that the jury was entitled to resolve a conflict, if any existed, between them, and that any inferences to be drawn from that testimony must be drawn adversely to Safety.

(ii) *Printed Publication*

The jury found (question No. 26) that Safety failed to prove that the chair claimed in the '586 patent was present in its entirety in Kamenetz, *The Wheelchair Book: Mobility for the Disabled* (1969) (*The Wheelchair Book*). The district court held that The Wheelchair Book "clearly discloses" all five elements of claims 5 and 6 of the '586 patent.

Orthokinetics' witnesses testified that the structure disclosed in *The Wheelchair Book* does not include "a head restraint which coacts with the scoliosis pads to exert therapeutic pressure on the spine," as set forth in the claims, particularly because the "head rest" in *The Wheelchair Book* is only a head rest and not a "head restraint" at all. A reasonable jury could clearly have found from that testimony that *The*

Wheelchair Book does not anticipate the claimed inventions because it discloses no "head restraint"

and certainly no "head restraint which coacts with the scoliosis pads to exert therapeutic pressure on the spine."

The district court correctly determined that *The Wheelchair Book* shows "headrests, headcushions, headwings and special head supports (including slings, caps, and collars)." That the reference shows those items, however, is simply no basis for finding anticipation. The claims require "head restraints" that are not shown by the reference. The district court was in no position to conclude that headwings embrace the head like a head restraint. Orthokinetics' expert, Professor Cherry, testified that headwings normally "support" the head, but do not "restrain" it. Because anticipation requires the disclosure in a prior art reference of each and every element as set forth in the claim, *Kalman v. Kimberly-Clark Corp* ., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir. 1983), cert. denied , 465 U.S. 1026 [224 USPQ 520] (1984), *The Wheelchair Book* cannot anticipate the claimed inventions set forth in claims 5 and 6. *See RCA Corp. v. Applied Digital Data Systems, Inc* ., 730 F.2d 1440, 221 USPQ 385 (Fed.Cir.), *cert. dismissed* , 468 U.S. 1228 (1984).

There being substantial evidence capable of supporting the jury's finding of no anticipation, and thus a failure of Safety to prove anticipation, the granting of Safety's motion for JNOV on anticipation by *The Wheelchair Book* must be *reversed.*

(iii) *Obviousness*

The jury concluded (question Nos. 27-29) that Safety had failed to prove by clear and convincing evidence that the inventions set forth in claims 5 and 6 would have been obvious to persons of ordinary skill in any of a number of arts, including a person "with mechanical skills who has the knowledge of the needs of handicapped children." The district court said that "[t]he jury's answers to [those questions] were without foundation in the evidence."

Again the district court focused on evidence in support of Safety's burden. Noting that Orthokinetics' disclaimer of claims 1-4 was in light of U.S. Patent No. 3,640,571, to Michael Keropian (Keropian), that Keropian disclosed all the elements recited in claims 1-4, and finding that *The Wheelchair Book* , H. Willard & C. Spackman, Occupational Therapy (4th ed. 1971), and U.S. Patent No. 3,269,768 to John C. Kinney (Kinney) disclose "head restraints", the district court concluded that it would have been obvious to add the "headrests to the Keropian scoliosis system, or to add the Keropian vertically adjustable torso system to the Kinney head rest and chair mechanism." With those references, the court concluded, "a person of ordinary skill in the art . . . would easily have been able to produce the structure defined by the ['586] patent."

Acceptance of the district court's foregoing analysis would make the conduct of the jury trial a pointless exercise. In accord with its instructions, the jury necessarily concluded that the combining of individual items picked from the references as later done by the district court, would not have produced the claimed inventions or would not have been obvious when the invention was made. No basis or reason exists in the record for the district court to have substituted its contrary conclusion. The jury heard the testimony of Safety's own witness, Professor Cherry, who testified on the improvements contributed in the '586 patent. Those improvements did not consist of a mere combining of a "head rest" with Kinney's scoliosis system; they contributed a *coaction* between the pads and a head *restraint* to provide therapeutic pressure at three points. Moreover, that the claims do not contain the phrase "three-point positioning" is not material, the coaction between the pads being effective to produce that result. *See In re Antonie* , 559 F.2d 618, 619, 195 USPQ 6, 8 (CCPA 1978) (claims need not recite inherent advantages relied on for patentability).

Moreover, the district court's analysis employed an inappropriate "would have been able to produce" test. The statute, § 103, requires much more, i.e., that it would have been *obvious* to produce the claimed invention at the time it was made without the benefit of hindsight.

The jury also found (question Nos. 34-37) that Orthokinetics had proved by a preponderance of the evidence that certain objective indicia support the validity of the '586 patent, i.e., unsuccessful attempts by others, long felt need, and commercial success. Though the district court viewed those jury findings as "without factual foundation," the record reflects substantial evidence on which a reasonable jury could have made each of those findings.

Because the district court erred in setting aside the jury's verdict that the inventions set forth in claims 5 and 6 would not have been obvious, the grant of Safety's motion for JNOV on the validity of the '586 patent must be *reversed*.

D. *The '867 Patent*

(i) *Indefiniteness*

The jury found (question No. 51) that Safety failed to prove by clear and convincing

Page 1088

evidence that the '867 patent was invalid because of claim language that does not particularly point out and distinctly claim the invention. 35 U.S.C. § 112, 2d¶ . The district court determined otherwise and granted Safety's motion for JNOV.

Claim 1, from which the rest of the claims depend, contains the limitation: "wherein said front leg portion is *so dimensioned* as to be insertable through the space between the doorframe of an automobile and one of the seats thereof."

Noting the testimony of Orthokinetics' expert, Mr. Hobbs, who said the dimensions of the front legs depend upon the automobile the chair is designed to suit, the district court stated:

> In response to this testimony, which clearly and convincingly establishes that claim 1 of the ['867] patent does not describe the invention in "full, clear, concise and exact terms," Orthokinetics points only to the conclusory statements of Hobbs, Gaffney and expert witness William McCoy, Jr., that the patent is, in fact definite. These conclusory statements are not an adequate basis for the jury to reject Safety's defense. The undisputed, specific testimony of Gaffney and Hobbs demonstrates that an individual desiring to build a non-infringing travel chair cannot tell whether that chair violates the ['867] patent until he constructs a model and tests the model on vehicles ranging from a Honda Civic to a Lincoln Continental to a Checker cab. Without those cars, "so dimensioned" is without meaning.

[2] The foregoing statement employs two measures impermissible in law: (1) it requires that claim 1 "describe" the invention, which is the role of the disclosure portion of the specification, not the role of the claims; and (2) it applied the "full, clear, concise, and exact" requirement of the *first* paragraph of § 112 to the claim, when that paragraph applies only to the disclosure portion of the specification, not to the claims. *Standard Oil Co. v. American Cyanamid Co* ., 774 F.2d 448, 453, 227 USPQ 293, 297 (Fed.Cir. 1985). The district court spoke, inappropriately, of indefiniteness of the "patent," and did not review the *claim* for *indefiniteness* under the *second* paragraph of § 112.

A decision on whether a claim is invalid under § 112, Id ¶ , requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Seattle Box Co. v. Industrial Crating & Packing Inc* ., 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed.Cir. 1984); *In re Morasi* , 710 F.2d 799, 803, 218 USPQ 289, 292 (Fed.Cir. 1983).

It is undisputed that the claims require that one desiring to build and use a travel chair must measure the space between the selected automobile's doorframe and its seat and then dimension the front legs of the travel chair so they will fit in that particular space in that particular automobile. Orthokinetics' witnesses, who were skilled in the art, testified that such a task is evident from the specification and that one of

ordinary skill in the art would easily have been able to determine the appropriate dimensions. The jury had the right to credit that testimony and no reason exists for the district court to have simply discounted that testimony as "conclusory".

The claims were intended to cover the use of the invention with various types of automobiles. That a particular chair on which the claims read may fit within some automobiles and not others is of no moment. The phrase "so dimensioned" is as accurate as the subject matter permits, automobiles being of various sizes. *See Rosemont, Inc. v. Beckman Instruments, Inc* ., 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed.Cir. 1984). As long as those of ordinary skill in the art realized that the dimensions could be easily obtained, § 112, 2d ¶ requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

Compliance with the second paragraph of § 112 is generally a question of law. *Shatterproof Glass Corp. v. Libbey Owens Ford Co* ., 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed.Cir.), cert. dismissed , 106 S.Ct. 340 (1985). On the record before us, we observe no failure of compliance with the statute, and thus no basis on § 112 grounds for disturbing the jury's verdict. The district court's grant of Safety's motion for JNOV for claim indefiniteness was in error and must be *reversed*.

(ii) *Obviousness*

The jury made numerous findings (question Nos. 39-48) all in support of its conclusion that Safety failed to prove by clear and convincing evidence that the inventions set forth in claims 1-5 of the '867 patent would have been obvious when they were made in view of the prior art to one of ordinary skill in the art.

Having outlined the prosecution history of the '867 reissue patent, the district court stated:

> Analysis begins with Gaffney's concession to the [U.S. Patent and Trademark Office] that [U.S. Patent No. 1,693,633 issued to Sarah Allen (Allen)] fully anticipated the original Gaffney patent, rendering that patent void under § 102. Therefore, the only novel aspects of the reissue patent [i.e. the '867 patent] claims are those portions of such claims which differ from the language of the original patent. Claim 1 added to original Claim 1 a "retractor means for assisting the attendant in retracting said rear wheel assembly . . . while the front leg is supported on the automobile. . . ."

The district court quoted the language added by reissue in claims 2-5 *supra* , and focused on the differences between the reissued '867 claims and those of the original '229 patent. Claims 3-5 were also characterized as adding "minor details."

It is not altogether clear from the passage quoted above whether the district court was comparing the claims of the '867 patent with Allen or with the original patent. A careful reading of the district court's opinion, and its amendments, however, makes clear that the claims of the original patent were applied as prior art against the '867 patent. That was legal error for the reasons discussed in *Interconnect Planning Corp. v. Feil* , 774 F.2d 1132, 1137, 227 USPQ 543, 546-47 (Fed.Cir. 1985), and Safety's attempt to distinguish that case is unpersuasive.

If the district court compared the '867 claims with the Allen patent, that comparison was based on an erroneous presumption, i.e., that Gaffney made a "concession" that Allen anticipated the claims of the original patent. Gaffney's reissue oath stated only that he believed "the original patent to be wholly or partly inoperative or invalid because claims 1 and 11 are unpatentable over [Allen]." 35 U.S.C. § 251; *see* 37 C.F.R. § 1.175(1)(1985); *Manual of Patent Examining Procedure* 1414 (5th ed. 1983). That is not, as Safety calls it, a "binding admission" of anticipation. In fact, even a cursory review of the Allen patent shows on its face that the jury could readily have found that it does *not* disclose each element of Gaffney's original patent.

The district court stated (underscoring indicates amendments adding to the court's original opinion;

brackets indicate amendments deleting from the court's original opinion):

> Given the jury's findings with respect to the level of ordinary skill in the art, the proper scope and content of the prior art and its details as summarized above, and assuming that the jury's general verdict constitutes a sufficient finding concerning the differences between the prior art and the Gaffney reissue patent claims, the question for this Court is whether any reasonable basis existed for [finding those differences] *their finding* . On consideration, it is eminently clear that no such basis exists -- that is, that all the differences between claims 1 through 5 of the Gaffney reissue patent [are] *and the prior art are such that the claimed invention as a whole would have been* obvious in light of the prior art *to one of ordinary skill in the art at the time of the Gaffney invention* . [Footnotes omitted.]

The district court's amendment changing "the differences are obvious" to "the claimed invention as a whole would have been obvious to one of ordinary skill at the time of the invention" substituted the correct statutory criteria, § 103, for the unauthorized "differences are obvious" standard. Despite that change, however, it is clear from the entire record and from a study of the amended opinion in its entirety, that the court substituted its view for that of the jury on the basis of its belief that the presence of individual elements in separate prior patents required a conclusion of obviousness.

The court concluded that (emphasis added):

> clear and convincing evidence demonstrates that in 1972 the holder of a college degree in engineering with experience in the wheel chair fields, presented with the Allen patents and the other patents described above, would doubtless have been *able* to produce the structure defined in claims 1 through 5 of the Gaffney reissue patent; *no probative evidence to the contrary* was presented to the jury. The *prior art suggests the combination both expressly and by implication* , and *no original new* patent's *result* is achieved which is not suggested by the combinations. Applying the *Railroad Dynamics* test, this Court concludes that the jury's implied conclusion that there were differences between the prior art and the claims in issue is unsupported by substantial evidence.

As it did in respect of the '586 patent, the court applied its " *able* to produce" standard in place of the statutory "obvious" standard of § 103. There was probative evidence in support of the jury's conclusion (testimony of Hobbs, Gaffney, Kazik, Inouye, Pivacek). Neither the court nor any witness identified what in the references suggested their combination or what in the references would produce the results of the claimed inventions.

It is unclear whether the district court believed there were *no* differences between the claimed invention of the '867 patent and the prior art. Though the court listed no differences, it is *undisputed* that there are at least these differences: the combination of legs as lever for loading the chair into an

automobile and the retraction of the rear wheels by the attendant while the patient remains in the chair. The sole question, therefore, is whether that difference, which we must presume was found by the jury, constituted substantial evidence in support of its nonobvious conclusion.

A review of each of the five prior art references establishes unequivocally that there was substantial evidence in support of the jury's implied findings of those differences. That evidence plus the objective evidence of nonobviousness (commercial success, failure of others, long felt need) supply a fully adequate basis on which a reasonable juror could have concluded that the subject matter as a whole of the inventions claimed in the '867 patent would not have been obvious to one of ordinary skill in the art. Neither the record nor the district court's opinion provides a basis for the substitution of a conclusion to the contrary. Therefore, the district court's setting aside of the jury's verdict upholding claims 1-5 of the '867 patent must be *reversed*.

(2) *Infringement*

The jury found (question Nos. 1-4) that Orthokinetics had met its burden of proving by a preponderance of the evidence that the accused chairs constituted infringement of claims 5 and 6 of the '586 patent. The testimony of Gaffney and Inouye, which supports that finding, faced no cross-examination and went unrebutted by Safety. The district court correctly denied Safety's motion for JNOV on infringement of the '586 patent.

Safety's sole argument on appeal is directed to matter extraneous to claims 5 and 6 of the '586 patent and is clearly without merit.

The jury found (question No. 15) that Orthokinetics had proved by a preponderance of the evidence that the accused chairs constituted infringement of claims 1-5 of the '876 patent. Safety sought JNOV on this issue, arguing that the claims must be limited to a rigid front leg portion extending to the floor, or to a front leg portion having a caster and a caster board fixedly mounted thereon, the leg portion being no wider than 9 1/2 inches at the caster board.

Because Orthokinetics' completely contrary testimonial evidence was fully adequate to support the jury's findings, the district court correctly denied Safety's motion for JNOV on infringement of the '867 patent. For the same reason, Safety's motion for new trial on infringement was properly denied.

(3) *Personal Liability for Infringement*

The jury found (question Nos. 5-10, 18-23) that Chipman, Cole and Pivacek were personally liable for acts of direct infringement and for inducing infringement of both patents.

The district court held as a matter of law that, because the jury could not have reasonably found the corporate officers liable for willful infringement, it could not find them personally liable for any infringing acts of the corporations. In attempting to support that holding, Safety argues that good faith belief in invalidity, based solely on a dealer's report that a district court had held the original of the '867 patent invalid, precludes a finding of *any* personal liability. Because neither proposition has any basis in law, we must reverse the district court's grant of Safety's motion for JNOV on the corporate officers' personal liability.

The jury found the corporate officers liable for direct infringement, 35 U.S.C. § 271(a), as well as for inducing infringement, § 271(b). The district court's opinion did not treat the finding on inducement, but dealt only with general principles involved in imposition of personal liability for acts of a corporation. However, it is well settled that corporate officers who actively aid and abet their corporation's infringement may be personally liable for inducing infringement under § 271(b) regardless of whether the corporation is the alter ego of the corporate officer. *Power Lift, Inc. v. Lang Tools, Inc* ., 774 F.2d 478, 481, 227 USPQ 435, 437 (Fed.Cir. 1985).

[3] Corporate officers are presumably aware of what they are doing, and in that sense they can be said to have acted "willfully." However, that does not mean that their acts must rise to the level recognized by the law as constituting willfull infringement as a prerequisite for the imposition of personal liability for the corporation's direct infringement.

To determine whether corporate officers are personally liable for the direct infringement of the corporation under § 271(a) requires invocation of those general principles relating to piercing the corporate veil.

Infringement is a tort, *Carbice Corp. v. American Patents Development Corp* ., 283 U.S. 27, 33, 8 USPQ 211, 213 (1931), and officers of a corporation are personally liable for tortious conduct of the corporation if they personally took part in the commission of the tort or specially directed other officers, agents, or employees of the corporation to commit the tortious act. *See generally* 3A

W. Fletcher, *Cyclopedia of the Law of Private Corporations* § 1135 (rev. perm. ed. 1975). The cases are legion in which courts have recognized and imposed personal liability on corporate officers for participating in, inducing, and approving acts of patent infringement. *See, e.g., White v. Mar-bel, Inc* ., 509 F.2d 287, 185 USPQ 129 (5th Cir. 1975); *Rex Chainbelt, Inc. v. General Kinematics Corp* ., 363 F.2d 336, 150 USPQ 319 (7th Cir. 1966); *see generally* D. Chisum, *Patents* , § 16.06, at 16-76 to 16-85 (1986).

The evidence established the makeup and control of STC and Entron. Pivacek testified that he was at all material times the President and sole stockholder of Entron and that he elected its Board of Directors. He also testified that he is the President of STC and that he, Cole, and Chipman held all of STC's directorships and owned all of the stock in STC. The evidence firmly establishes that Pivacek, Cole and Chipman were directly responsible for the design and production of the infringing chairs and that they were the only ones who stood to benefit form sales of those chairs. That evidence was fully sufficient to support the jury's imposition of personal liability on Pivacek, Cole, and Chipman for the direct infringement of STC and Entron and for STC's contributory infringement. The district court's setting aside of the jury's findings on personal liability must therefore be *reversed.*

(4) Willful Infringement of the '867 Patent

Fed.R.Civ.P. 50(a) states that a "motion for a directed verdict shall state the specific grounds therefor." Rule 50(b) states that "a party who has moved for a directed verdict may move to have the verdict and any judgment entered thereon set aside and to have judgment entered *in accordance with his motion for a direct verdict* ." A specific reference to an issue in a motion for JNOV cannot preserve that issue for appeal where that issue was not specifically included in a motion for directed verdict made before the jury retired to consider its verdict. *See, e.g., Kinzenbaw v. Deere & Co* ., 741 F.2d 383, 387, 222 USPQ 929, 931 (Fed.Cir. 1984), cert denied , 470 U.S. 1004 (1985).

Faced with its failure to have moved for directed verdict on willful infringement, Safety argues that its motion for directed verdict on infringement encompasses willfulness. That argument is without merit. Infringement and willful infringement are not the same thing, and Rules 50(a) and 50(b) mandate specificity.

Alternatively, however, Safety says Orthokinetics cannot raise on appeal Safety's failure to include willfulness in its motion for directed verdict because Orthokinetics never objected to its inclusion in Safety's motion for JNOV before the district court.

Orthokinetics' reliance here on a page in its brief on the motion is insufficient because that page is not of record before us. Moreover, Orthokinetics' oral statements to the district court indicate that it never intended to contest the inclusion of the issue of willfulness in Safety's JNOV motion. Though the district court might well have refused consideration of willfulness on the motion for JNOV in light of Rule 50(b), it did not. In view of Orthokinetics' failure to raise an objection before the district court, we will consider the issue. *Cox v. City of Freeman, Missouri* , 321 F.2d 887, 891 (8th Cir. 1963).

The district court determined that, because Safety was told by a dealer of a district court's ruling in another case that the original '229 patent was invalid, (*Palmer v. Orthokinetics, Inc* ., 197 USPQ 207 (C.D. Cal. 1977), *rev'd* , 611 F.2d 316, 204 USPQ 893 (9th Cir. 1980)), no reasonable and fair minded juror could have found willful infringement, and set aside the jury's findings that STC, Entron, Cole, and Chipman willfully infringed the '867 patent.

A finding of willful infringement is based on a totality of the circumstances. *See, e.g., Kloster Speedsteel AB v. Crucible Inc* ., 793 F.2d 1565, 1579-80, 230 USPQ 81, 90-91 (Fed.Cir. 1986) and cases cited therein. It is not necessary to determine which combination of facts, among those established by substantial evidence at trial and recognized by this court as capable of contributing to a willfulness finding, were relied upon by the jury. This court, and the district court on the motion for JNOV, must

uphold the jury determination of willfulness if there is any set of facts supported by substantial evidence and capable of supporting that jury determination. *See, e.g., Shatterproof Glass Corp. v. Libbey-Owens Ford Co* ., 758 F.2d 613, 619, 225 USPQ 634, 636 (Fed.Cir.), cert. dismissed , 106 S.Ct. 340 (1985); *Railroad Dyanmics, Inc. v. A. Stucki Co* ., 727 F.2d 1506, 1512, 220 USPQ 929, 936 (Fed.Cir.), cert. denied , 469 U.S. 871 [224 USPQ 520] (1984).

In this case, substantial evidence supports the jury's finding (question No. 24) of willful infringement. The evidence shows that Safety did not consult an attorney until after Orthokinetics initiated this action. The district court's view that Safety could have relied on a dealer's report of a district court ruling in the *Palmer* case that the original

'229 patent was invalid and thus need not have consulted an attorney is insufficient in this case to set aside the jury's finding of willful infringement. Had Safety relied on that prior district court ruling, one might expect that it would have sought counsel when Orthokinetics informed Safety that that ruling had been *reversed* on appeal. *See Palmer v. Orthokinetics, Inc* ., 611 F.2d 316, 204 USPQ 893 (9th Cir. 1980), *rev'g* , 197 USPQ 207 (C.D. Cal. 1977). Instead, Safety merely continued to infringe. Moreover, Safety never replied to any of the letters sent by Orthokinetics and declined Orthokinetics' invitation to participate as a protester in the reissue proceedings.

The jury could properly have viewed the aforementioned evidence as sufficient to establish Safety's complete disregard of Orthokinetics' patent rights. Therefore, the district court's grant of JNOV on willfulness must be *reversed*.

The corporate officers being personally liable for the acts of the corporations, and the corporations being liable for willful infringement, the jury's finding that Cole and Chipman are willful infringers must be upheld.

(5) Patent Misuse

Because no prior art anticipated the claims of the '586 patent, Safety's assertion that Orthokinetics is guilty of patent misuse for asserting a patent, the '586 patent, that it knew was invalid under § 102(b), is without merit.

With respect to the '867 patent, the district court deemed Safety's confused series of assertions, involving the settlement agreement in the *Palmer* case and Palmer's customer, unworthy of analysis and insufficient to overcome the jury's finding (question no. 52) which the district court found to have been supported by substantial evidence. We agree.

The district court correctly denied Safety's motion for JNOV on patent misuse and Safety's motion for a new trial on that issue.

(6) Conditional Grant of a New Trial

This court must review a denial or grant of a motion for a new trial under an abuse of discretion standard. *Medtronic, Inc. v. Intermedics, Inc* ., 799 F.2d 734, 740-41, 230 USPQ 641, 645 (Fed.Cir. 1986); *Railroad Dynamics Inc* ., 727 F.2d at 1512, 220 USPQ at 935. "That question turns on whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair." *DMI, Inc. v. Deere & Co* ., 802 F.2d 421, 427, 231 USPQ 276, 280 (Fed.Cir. 1986); *see Witco Chemical Corp. v. Peachtree Doors, Inc* ., 787 F.2d 1545, 1548, 229 USPQ 188, 190 (Fed.Cir.), cert. dismissed , 107 S.Ct. 258 (1986).

The district court stated that "a new trial is compelled solely by the standards set forth in the Federal Circuit's post-trial *Structural Rubber Products [Co. v. Park Rubber Co* ., 749 F.2d 707, 223 USPQ 1264 (Fed.Cir. 1984)] case, when read in conjunction with applicable Sixth Circuit law on Fed.R.Civ.P.49(a)." The district court derived that "Sixth Circuit law" exclusively from "reading liberally," as it said, *Sakamoto*

v. N.A.B. Trucking Co ., 717 F.2d 1000, 1006 (6th Cir. 1983).

More specifically, the district court concluded that a new trial would be in order because: (1) the parties "were prejudiced by delivering closing arguments without the benefit of a final -- or even a substantially completed -- version of the special verdict," citing *Sakamoto* ; (2) the jury instructions and special verdicts failed to set forth what specific facts had to be found to support a general verdict on validity or infringement, citing *Sakamoto* and *Structural Rubber* ; and (3) "substantial injustice ensued from [the court's] efforts to determine the appropriate role of judge and jury at the same time that the Federal Circuit was generating a series of decisions examining the same topic." With respect to reason (3), the district court determined:

> Had counsel been aware that factual issues on validity were being submitted to the jury for binding verdicts, they might well have made different submissions, proposals and objections with respect to both the jury instructions and the special verdict. And had this Court been aware that the validity verdict would be binding, it certainly would have taken a different approach to the validity instructions and verdict.

The district court's reasons for a new trial are based on a speculative and overly expansive view of the case law. Moreover, it does not point to any specific flaws in the instructions as given, or what different proposals, objections, and approach would have been taken or justified.

Regarding reason (1), the *Sakamoto* court held that "the disclosure prior to final argument of at least the *substance* of the Rule 49(a) special verdict interrogatories and supplemental instructions is mandatory." 717 F.2d at 1006 (emphasis added). That court noted "that it may be an abuse of

discretion to fail to show the Rule 49(a) interrogatories to counsel in advance of argument where, because of exceptional circumstances, such as the complexity of the case, unfairness would otherwise result." However, the *Sakamoto* court determined that the appellant had shown to prejudice from the district court's failure to disclose the additional interrogatory before the summation. Nothing that counsel's failure to object or request further argument, and everyone's awareness of the issue represented by the additional interrogatory, established an absence of prejudice, the Sixth Circuit *affirmed* the district court's *denial* of a new trial.

Whether the present case may be categorized as falling within Rule 49(a) or Rule 49(b), *Sakamoto* makes clear that Safety must show actual prejudice, which it failed to do. Safety knew what the issues were from the filing of the pretrial briefs onward and certainly when it assisted with the jointly-prepared jury instructions before closing argument. Moreover, like the appellant in *Sakamoto* , Safety made no objection and no request for further argument.

Regarding reason (2), the district court determined that *Sakamoto* "indicates that a general verdict included together with special verdict questions is impermissible, or at best null." For the reasons set forth above, we do not read *Sakamoto* for that proposition.

The district court said *Structural Rubber* mandates "that a general verdict is valid only if it is the product of instructions which clearly lay out alternative mandatory general verdicts when specific facts are found." In this case, however, there was no objection to the instructions as failing to lay out alternative verdicts based on the evidence adduced.

In *Structural Rubber* , this court *remanded* for a partial new trial because instructions were given on issues on which no evidence was presented. The alternative mandatory verdict instructions discussed in *Structural Rubber* are desirable and facilitate both jury deliberations and appellate review. This court did not hold in that case that every general verdict is invalid if that particular type instruction was not given. Nor did it hold that a new trial is compelled in such instances when the parties have agreed to the instructions given.

Moreover, in the present case, the jury did not return a general verdict ("we find for the plaintiff"). It returned a series of hybrid special verdicts on each issue with answers to questions on what had and had not been proven.

In all events, non-objecting parties should not be forced to retry the case merely because the instructions and the form of verdict obtained from the jury did not match those involved in any earlier and different case, particularly where the party who failed to convince the jury has shown no prejudice emanating from the instructions given. *See Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp* ., 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed.Cir. 1984), cert. denied , 469 U.S. 1038 (1984).

Under Fed.R.Civ.P. 51, the failure of Safety to proffer timely, specific objections to the instructions precludes our consideration of any such objection on appeal absent great injustice. *Roberts v. City of Troy* , 773 F.2d 720, 723 (6th Cir. 1985); *Structural Rubber* , 749 F.2d at 714 & n.3, 223 USPQ at 1269 & n.3. Safety's sole timely objection may have been (assuming it was brought to the court's attention before the jury retired, *see Transcontinental Leasing, Inc. v. Michigan National Bank of Detroit* , 738 F.2d 163, 167 (6th Cir. 1984)) to the instruction stating the irrelevancy of the doctrine of prosecution history estoppel when the jury finds literal infringement. The district court correctly determined that instruction to have been proper. *See, e.g., Fromson v. Advance Offset Plate, Inc* ., 720 F.2d 1565, 1571, 219 USPQ 1137, 1141 (Fed.Cir. 1983). There is no merit in Safety's present contention that that instruction misled the jury into not construing the claims in light of the prosecution history, particularly when order instructions told the jury to do precisely that. Instructions must be read in their entirety. *See, e.g., Batesole v. Stratford* , 505 F.2d 804, 809 (6th Cir. 1974); *Grandsky v. Sperry Rand Corp* ., 489 F.2d 502, 503-04 (6th Cir. 1973).

Regarding reason (3), neither Safety nor the district court has indicated how or why the *jury* might have made different findings or reached different conclusions if *Safety* or the *court* had known the jury's verdicts on obviousness would be binding. Nothing of record indicates that either party or the court expected that any jury verdict would be merely "advisory" [1]This court had made clear, *before*] this trial, that jury verdicts in patent cases *are* binding. *See White v. Jef*

frey Mining Machinery Co ., 723 F.2d 1553, 1558, 220 USPQ 703, 705 (Fed.Cir. 1983). cert. denied , 469 U.S. 825 (1984); *Connell v. Sears, Roebuck & Co* ., 722 F.2d 1542, 1547, 220 USPQ 193, 197-98 (Fed.Cir. 1983). Having failed to carry its burden before one jury, Safety has shown no such actual prejudice as would warrant a second chance before a second jury and the consequent doubling of the burden on Orthokinetics and the district court.

---

[1] Nor is there any indication in the record that the jury was told that it would be serving in merely an "advisory" capacity. That jurors are unlikely to appreciate the taking of weeks out of their lives, only to have the result of their close attention and deliberations treated as merely "advisory" may account for the extreme rarity of use of advisory juries under Fed.R.Civ.P. 39(c).

The case was fully and fairly litigated, the instructions and interrogatories (to which Safety did not object) were jointly prepared and fully adequate to guide the jury in its consideration of the evidence presented. There exists no newly-discovered *material* evidence. A new trial would therefore be unwarranted. The district court's conditional grant of a new trial was an abuse of discretion and must be vacated.

CONCLUSION

The judgment entered in response to those of Safety's motions for JNOV that were granted is *reversed.*

The judgment entered on the jury verdict in light of the denial of Safety's other motions for JNOV is *affirmed*. The district court's denial of Safety's motion for a new trial on infringement and misuse is affired. The district court's conditional grant of a new trial on validity is vacated.

The case is *remanded* for entry of judgment on the jury's verdicts, for issuance of an appropriate permanent injunction against infringement by Safety, for an accounting, and for such further proceedings not inconsistent with this opinion as the district court may deem necessary.

AFFIRMED IN PART, VACATED IN PART, REVERSED IN PART, AND REMANDED

APPENDIX

Question 2

Do you find that Orthokinetics has proved by a preponderance of the evidence that defendant, Safety Travel Chairs, Inc., has directly infringed the following claims of the ['586] patent by sale of Safety TranSporter Chair Models with adjustable scoliosis pads? Please answer: "proved" or "not proved" as to each claim:

Claim 5 " *Proved* "

Claim 6 " *Proved* "

Question 5

Do you find that Orthokinetics has proved by a preponderance of the evidence that the defendant, Clarke Chipman, is personally liable for direct infringement of the ['586] patent?

Please answer: "Proved" or "not proved":

" *Proved* "

Question 24

Do you find that Orthokinetics has proved by a preponderance of the evidence that the infringement of the ['867] patent by any of the following defendants was willful?

Please answer: "proved" or "not proved":

Safety " *Proved* "

Entron " *Proved* "

William Cole " *Proved* "

Clark Chipman " *Proved* "

Question 31

Have Safety *et al* . proved by clear and convincing evidence that the ['586] patent is invalid becuase the subject matter of claims 5 and 6 was publicly used or offered for sale more than one year before the December 4, 1972 filing of the ['586] patent application?

Please answer: "proved" or "not proved":

" *Not proved* "

Question 40

Do you find that Safety *et al* . have proved by clear and convincing evidence that the ['867] patent is invalid because the differences, if any, between the prior art and the claimed subject matter, taken as a whole, would not have been obvious to one of ordinary skill in the art the time the claimed invention was made?

Please answer: "proved" or "not proved" as to each claim of the ['867] patent:

Claim 1 " *Not proved* "

Claim 2 " *Not proved* "

Claim 3 " *Not proved* "

Claim 4 " *Not proved* "

Claim 5 " *Not proved* "

- End of Case -

Intellectual Property Library
ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Metabolite Laboratories Inc. v. Laboratory Corp. of America Holdings, 71 USPQ2d 1081 (Fed. Cir. 2004)

Metabolite Laboratories Inc. v. Laboratory Corp. of America Holdings, 71 USPQ2d 1081 (Fed. Cir. 2004)

71 USPQ2d 1081
Metabolite Laboratories Inc. v. Laboratory Corp. of America Holdings
U.S. Court of Appeals
Federal Circuit
No. 03-1120
Decided June 8, 2004
370 F3d 1354

Headnotes

PATENTS

[1] Patent construction — Claims — Broad or narrow (▶125.1303)

Patent construction — Claims — Process (▶125.1309)

Step of claimed method for detecting deficiencies in B vitamins, which states that method must "correlate" elevated level of amino acid homocysteine in body fluid with deficiency of cobalamin or folate, is properly construed to require establishment of mutual or reciprocal relationship between elevated homocysteine level and vitamin deficiency, and does not require showing of separate hematologic or neuropsychiatric symptom to confirm such "correlation," since claim language only requires association of homocysteine levels with vitamin deficiencies, and says nothing about confirmatory step or further correlation beyond stated relationship, since claim's preamble restates that invention detects vitamin deficiencies without relating those deficiencies to any particular abnormality, since prosecution history, which ties preamble directly to "correlating" step, supports this construction, and since specification shows that claim language does not require confirmation that elevated homocysteine level has caused some deleterious symptom or abnormality.

[2] Infringement — Inducement (▶120.15)

Substantial evidence supports jury's conclusion that defendant induced infringement of plaintiffs' patented method for detecting deficiencies in B vitamins, since record shows that physicians perform "correlating"step of claimed method by ordering assays of amino acid homocysteine from defendant and correlating results of those assays, thereby directly infringing asserted claim, and since evidence of defendant's intent to induce infringement is provided by defendant's publications, which state that elevated total homocysteine correlates

with cobalamin/folate deficiency, and recommend treatment of deficiency with vitamin supplements.

[3] Patentability/Validity — Specification — Written description(▶115.1103)

Patentability/Validity — Specification — Enablement(▶115.1105)

Patentability/Validity — Specification — Claim adequacy(▶115.1109)

Claimed method for detecting deficiencies in B vitamins, which includes step of "correlating" elevated

level of amino acid homocysteine in body fluid with deficiency of cobalamin or folate, is not invalid for indefiniteness, lack of adequate written description, or lack of enablement, since claim construction proceedings in federal district court produced discernible and clear meaning for "correlating" term, since there is substantial evidence that persons of ordinary skill in art understood from specification that inventors possessed "correlating"step at time they filed patent application, and since record shows repeatedly that "correlating" step is well within knowledge of those of skill in art, in that step is simple conclusion that vitamin deficiency exists if assay shows elevated level of total homocysteine.

[4] Patentability/Validity — Anticipation — Identity of elements (▶115.0704)

Claimed method for detecting deficiencies in B vitamins, which includes step of "correlating" elevated level of amino acid homocysteine in body fluid with deficiency of cobalamin or folate, is not anticipated by prior art reference under 35 U.S.C. § 102, since reference does not recite all limitations of claim at issue, since reference does not specifically mention vitamin B deficiencies, and at most discloses no more than broad genus of potential applications for its discoveries, since reference that discloses genus does not inherently disclose all species within that broad category, and since U.S. Patent and Trademark Office considered cited reference in allowing claims.

[5] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Patentability/Validity — Obviousness — Secondary considerations generally (▶115.0907)

Claimed method for detecting deficiencies in B vitamins, which includes step of "correlating" elevated level of amino acid homocysteine in body fluid with deficiency of cobalamin or folate, is not obvious in view of prior art reference when combined with other references disclosing that partial homocysteine assays could help diagnose vitamin B deficiency, since U.S. Patent and Trademark Office considered primary reference and all but one of secondary references in allowing claims, and sole reference not considered by patent examiner is cumulative of others, since secondary references refer to homocystine rather than total homocysteine, and thus do not add considerably to primary reference's disclosure, since record does not show that person of ordinary skill in art would have been motivated to combine references, and since record contains objective indicia, including initial skepticism about invention and patentee's licensing of invention to eight companies, that support conclusion of nonobviousness.

[6] Title — License (▶150.05)

JUDICIAL PRACTICE AND PROCEDURE

Jurisdiction — Subject matter jurisdiction — Case or controversy (▶405.0703)

Plaintiffs' claim that defendant's "panel test"infringes claim of patent for method of detecting deficiencies in B vitamins does not present real case or controversy, since it is undisputed that license is still in effect as to panel tests performed by defendant, since such license constitutes licensor's covenant not to sue licensee, and covenant not to sue deprives court of declaratory judgment jurisdiction, and since licensor that has implicitly covenanted not to sue licensee by virtue of license agreement itself therefore cannot seek declaratory judgment of infringement; moreover, defendant cannot challenge validity of patent claim for which it continues to pay royalties.

PATENTS

[7] Infringement — Willful (▶120.16)

REMEDIES

Monetary — Damages — Patents — Increased damages(▶510.0507.07)

Federal district court did not abuse its discretion in awarding enhanced damages for defendant's willful infringement of patent for method of detecting deficiencies in B vitamins, since evidence that defendant obtained opinion from its discipline director, who is not patent attorney and who did not consult patent itself, supports finding that defendant did not conduct reasonable investigation into potential infringement by accused method, since terms of agreement licensing accused method to defendant specifically exclude patent in suit from warranty covered by agreement's indemnity provision, and defendant therefore knew or should have known that third-party licensor believed use of accused method might infringe patent, since defendant is large company with extensive financial means, and since defendant's infringing activities with respect to claim at issue began in 1998 without any attempts to remedy infringement; district court's failure to explicitly set forth its rationale for awarding enhanced damages is not fatal to its decision, since it is readily apparent from appellate record that district court likely considered at least four factors from enhanced damages analysis in deciding to double infringement award.

Particular Patents

Particular patents — Chemical — Vitamin deficiency tests

4,940,658, Allen, Stabler, and Lindenbaum, assay for sulfhydryl amino acids and methods for detecting and distinguishing cobalamin and folic acid deficiency, judgment of willful infringement affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the District of Colorado, Weinshienk, S.J.

Action by Metabolite Laboratories Inc. and Competitive Technologies Inc. against Laboratory Corp. of America Holdings, d/b/a LabCorp, for patent infringement and breach of license agreement. Following jury verdict for plaintiffs, district court denied defendant's motion for judgment as matter of law, doubled award of infringement damages, and entered permanent injunction, and defendant appealed. Affirmed; Schall, J., concurring in part and dissenting in part in separate opinion.

Attorneys

Glenn K. Beaton, J. Gregory Whitehair, and Amanda J. Tessar, of Gibson, Dunn & Crutcher, Denver, Colo.; Mark A. Perry, Washington, D.C., for plaintiffs-appellees.

Jonathan S. Franklin and Catherine E. Stetson, of Hogan & Hartson, Washington; John P. Higgins, of Alston & Bird, Charlotte, N.C., for defendant-appellant.

Judge

Before Rader, circuit judge, Friedman, senior circuit judge, and Schall, circuit judge.

Opinion Text

Opinion By:

Rader, J.

In the United States District Court for the District of Colorado, a jury found that Laboratory Corporation (LabCorp) indirectly infringed Metabolite Laboratories, Inc.'s (Metabolite's) U.S. Patent No. 4,940,658 (the '658 patent). The jury also found that LabCorp partially breached its contract with Metabolite. Based on

this verdict, the district court assessed damages of $3,652,724.61 for breach of contract and $1,019,365.01 for indirect infringement. *Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D. Colo. Dec. 3, 2001). After denying LabCorp's motion for judgment as a matter of law (JMOL), the district court doubled the infringement award for willful infringement and issued a permanent injunction. *Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D. Colo. Nov. 19, 2001). Because the record supports the jury's verdicts and the trial court's decisions, this court affirms.

I.

The '658 patent claims methods for detecting cobalamin or folate deficiency. Cobalamin and folate are both B vitamins, commonly known as B_{12} and folic acid, respectively. A deficiency in these vitamins can cause serious illnesses in humans, including vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency.

Because these B vitamins assist in metabolizing the amino acid homocysteine, scientists directly assayed homocysteine to screen for cobalamin and folate deficiency. These direct homocysteine assays were unreliable. Then researchers at University Patents Inc. (UPI) discovered a relationship between elevated

levels of total homocysteine and a deficiency in either cobalamin or folate. The total homocysteine test, however, could not alone identify which vitamin was deficient. Total homocysteine includes free and protein-complexed homocysteine and also includes homocysteine derivatives homocystine and homocysteine-cysteine.

Originally, doctors could not conveniently treat both deficiencies because while folate was available in tablet form, cobalamin could only be administered by injection. After cobalamin became available in tablet form, however, doctors could simply order a total homocysteine test and, without identifying the deficient vitamin, treat elevated levels of total homocysteine with a tablet containing both cobalamin and folate. The UPI inventors also developed a test to identify the deficient vitamin using methylmalonic acid (the panel test method). The '658 patent claims both the total homocysteine test and the total homocysteine-methylmalonic acid test.

Claim 13 claims the total homocysteine test:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

'658 patent, col. 11, ll. 58-65.

UPI's successor, Competitive Technologies Inc., licensed the patent to Metabolite, which in turn sublicensed the patent to Roche Biomedical Laboratories (now LabCorp). LabCorp, a laboratory testing company, originally performed total homocysteine assays under the sublicense. But in 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories (Abbott test)and discontinued royalty payments to Metabolite for total homocysteine assays.

In response, Metabolite sued LabCorp for infringement. The district court construed the disputed claim terms, and the case proceeded to a jury. The jury found that LabCorp breached its license agreement with Metabolite, that LabCorp willfully infringed the '658 patent, and that the claims at issue are not invalid. The jury assessed damages against LabCorp of $3,652,724.61 for breach of contract and $1,019,365.01 for infringement. The district court entered judgment against LabCorp and awarded

damages as assessed by the jury.

After the trial, the district court denied LabCorp's motion for JMOL on infringement, breach of contract, invalidity, and willful infringement. In light of the finding of willfulness, the district court doubled the jury's infringement award to $2,038,730.02. The district court also permanently enjoined LabCorp from using the homocysteine-only test. LabCorp appeals the district court's claim construction as well as the denial of JMOL.

II.

Claim construction is a matter of law that this court reviews without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 [46 USPQ2d 1169] (Fed. Cir. 1998) (en banc). The jury's finding of infringement, however, raises questions of fact, which this court reviews for substantial evidence. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1348-49[55 USPQ2d 1161](Fed. Cir. 2000).

This court reviews a denial of JMOL without deference by reapplying the JMOL standard. Thus, this court will affirm a denial of JMOL unless substantial evidence does not support the jury's factual findings or the verdict rests on legal errors. *Waner v. Ford Motor Co.*, 331 F.3d 851, 855 [66 USPQ2d 1943](Fed. Cir. 2003).

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, paragraph 1, is a question of fact that this court reviews for substantial evidence. *Union Oil v. Atl. Richfield Co.*, 208 F.3d 989, 996 [54 USPQ2d 1227](Fed. Cir. 2000). Enablement is a matter of law that this court reviews without deference; however, this court reviews the factual underpinnings of enablement for substantial evidence. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1371-72 [67 USPQ2d 1692] (Fed. Cir. 2003). Similarly, this court reviews the legal determination of obviousness without deference, but reviews its factual underpinnings for substantial evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 [63 USPQ2d 1374] (Fed. Cir. 2002). This court reviews a legal finding of indefiniteness without deference. *BJ Servs.*, 338 F.3d at 1371-72. Whether a prior art reference anticipates a patent is a factual determination that this court reviews for substantial evidence. *Teleflex*, 299 F.3d at 1323.

Whether infringement was willful is a question of fact that this court reviews for substantial evidence. *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1346 [57 USPQ2d 1953] (Fed. Cir. 2001). This court reviews an award of enhanced damages and grant of a permanent injunction for abuse of discretion. *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1272 [51 USPQ2d 1225] (Fed. Cir. 1999).

III.

Infringement

The primary challenge to the jury's indirect infringement verdict requires this court to review the district court's construction of the claim term "correlating." The infringement inquiry is a two-step process. This court construes the disputed claim terms and then compares the properly construed claims to the accused device. *Cybor Corp.*, 138 F.3d at 1454. Thus, this court first reviews the district court's claim construction.

As always, the claim language itself governs its meaning. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 [39 USPQ2d 1573] (Fed. Cir. 1996). This court construes the meaning of claim language according to its usage and context. *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1378 [68 USPQ2d 1619] (Fed. Cir. 2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of invention. *See Rexnord Corp.*

v. Laitram Corp., 274 F.3d 1336, 1342 [60 USPQ2d 1851](Fed. Cir. 2001). Indeed, normal rules of usage create a "heavy presumption"that claim terms carry their accustomed meaning in the relevant community at the relevant time. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 [62 USPQ2d 1658] (Fed. Cir. 2002) (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 [50 USPQ2d 1607] (Fed. Cir. 1999)). Thus, this court sets the meaning of claim terms by ascertaining their technological and temporal context.

In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1347 [65 USPQ2d 1961](Fed. Cir. 2003) (citing *Teleflex*, 299 F.3d at 1325-26). In other words, a patent applicant may define a term differently from its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. *Id.* Therefore, the primary aids to supply the context for interpretation of disputed claim terms are in the intrinsic record. *Vitronics*, 90 F.3d at 1582 (Fed. Cir. 1996).

Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term. *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1388 [65 USPQ2d 1138] (Fed. Cir. 2002) (a patent applicant may "clearly and unambiguously" disavow claim scope during prosecution).

This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 [51 USPQ2d 1161] (Fed. Cir. 1999) ("[C]onsultation of extrinsic evidence is particularly appropriate to ensure that [the court's]understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art."); *Vitronics*, 90 F.3d at 1585. Another excellent source of context for disputed terms is dictionary definitions and treatises. *See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202[64 USPQ2d 1812](Fed. Cir. 2002) ("[D]ictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.").

As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306, 1315 [66 USPQ2d 1429] (Fed. Cir. 2003) ("Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); *Ferguson Beauregard v. Mega Sys., LLC*, 350 F.3d 1327, 1338 [69 USPQ2d 1001] (Fed. Cir.

2003) ("The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art."); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 [59 USPQ2d 1401] (Fed. Cir. 2001) ("[I]t is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art."); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 [34 USPQ2d 1321] (Fed. Cir. 1995) (en banc) ("[T]he focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). In this case, as evidenced by the jury instruction, the parties agreed that the level of ordinary skill in this field of invention was "a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases."

The disputed term "correlating" appears in the second step of claim 13, which states: "[C]orrelating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." In its *Markman* brief below, LabCorp urged the district court to construe "correlate"according to its dictionary definition as a verb meaning "to establish a mutual or reciprocal relation of" an elevated level of

homocysteine. LabCorp further argued that the district court should construe the "correlating"step as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropyschiatric abnormality,"or "[a] deficiency of folate which causes a hematologic abnormality."The district court adopted LabCorp's dictionary definition by construing "correlating"to mean "to establish a mutual or reciprocal relationship between,"but declined to "include a reference to hematologic or neuropsychiatric abnormality" in order to avoid impermissibly importing a limitation from the specification.

On appeal, LabCorp argues that claim 13's correlating step should be construed as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality,"or a "deficiency of folate which causes a hematologic abnormality."LabCorp interprets the specification to clearly define a "deficiency of cobalamin" as the presence of a clinical or hematologic syndrome or both that responds to cyano-cobalamin treatment, and to acknowledge that some clinical or hematologic syndrome or neuropsychiatric abnormality must be present. Thus, LabCorp contends that the correlation step of claim 13 should be construed to require a showing of a separate hematologic or neuropsychiatric symptom to confirm the "correlation."

[1] The claim states that the method must correlate "an elevated level of total homocysteine ... with a deficiency of cobalamin or folate." This language does not require a further association between the level of total homocysteine and either a hematologic or neuropyschiatric abnormality or both. The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies. The claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship.

The preamble further supports the district court's reading of the claim: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals."This language restates that the invention detects vitamin deficiency. This introductory language does not relate those deficiencies to any particular abnormality. A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 [62 USPQ2d 1781] (Fed. Cir. 2002) (in rare circumstances, a preamble's recitation of intended use may serve to distinguish the prior art).

An examination of the prosecution history of this patent brings the meaning of the preamble into focus. As originally filed, claim 13 did not contain the "correlating"step. The examiner rejected claim 13 under 35 U.S.C. § 112 because it did not "recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample with, etc. The final step should be clearly related to the preamble of the claim." Rather than add a second step as the examiner suggested, however, the applicant responded: "[A]s applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." After this response, the examiner dropped the § 112 objection,

but rejected claim 13 under § 102: "In the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention. The claim lacks a positive limitation for correlating to a particular condition and has only one method step recited." At that point, the applicant added the recommended "correlating"step. The examiner then allowed claim 13.

This prosecution history ties the preamble directly to the "correlating"step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency. "Detecting"in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. For example, the results of a pregnancy test can either be positive or negative. Either result is informative to the patient. Similarly, in this case, the assaying step can identify an elevated or an unelevated level of total homocysteine. Then the "correlating"step can identify, in cases of elevated levels, a relationship or not to vitamin deficiency. The results in either the assaying or

correlating steps are informative. Thus, the preamble supports the district court's construction that "correlating"includes ascertaining either a mutual or reciprocal relationship between total homocysteine and a vitamin deficiency. The preamble does not require this invention to show a further association with an abnormality.

The specification confirms that the claim language does not require as part of the method a confirmation that the elevated level causes some deleterious symptoms or abnormalities. LabCorp points to portions of the specification that discuss the relationship between the elevated levels and either clinical or hematologic symptoms. *See, e.g.*, '658 patent, col. 10, ll. 56-61; col. 12, ll. 8-15. LabCorp would expand those references to require some confirmatory step in the claim. The specification, however, does not require such a confirmatory step. Rather, the specification at one juncture acknowledges that the method can show vitamin deficiency without any clinical symptoms: "These findings led us to conclude that large numbers of patients with cobalamin deficiency lack the 'typical' clinical and hematologic features usually expected to be present in cobalamin deficiency ...." *Id.* at col. 11, ll. 40-45. In other words, the specification shows that the method can show an association between elevated levels and vitamin deficiency without any further clinical symptoms. Thus, the district court properly refused to import into the claims LabCorp's proposed limitation from the specification. The specification itself does not support such a limitation on the meaning of the claims.

As noted earlier, the district court construed "correlating" to mean a "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies. The inventors discovered that assaying total homocysteine correlated with (or predicted relatively accurately) whether a patient had a deficiency of cobalamin or folate. *Id.* at col. 4. ll. 17-23; col. 10, ll. 35-42. The specification explains that an elevated level of total homocysteine often indicates a deficiency, while a non-elevated level indicates no deficiency. For example, the overview of the invention notes: "This invention pertains to ... methods for determining whether said warm-blooded animal has a cobalamin deficiency, a folic acid deficiency, *neither*, or both." *Id.* at col. 1, ll. 13-15 (emphasis added). Next, in the summary of the invention, the patentee stated: "Accordingly, assays for homocysteine can be used to determine the *presence or absence* of cobalamin and/or folic acid deficiency in warm-blooded animals." *Id.* at col. 5, l. 66 - col. 6, l. 1 (emphasis added). This court observes that the perfect symmetry between "mutual or reciprocal" and "presence or absence" shows that the district court correctly placed the term "correlating"in its proper context with its proper meaning.

Finally, the patentee explained:

> Once folate and/or cobalamin deficiency has been determined, the progress of treatment can be monitored by repeating the assays periodically during and after treatment. A drop in the level of homocysteine in the serum and/or urine after oral or parenteral adminstration of cobalamin and/or folate as the case may be confirms the diagnosis.

Id. at col. 10, ll. 18-24. This recitation confirms that the patentee anticipated assays without an elevated level of total homocysteine, i.e., the reciprocal relationship, would further confirm the diagnosis by showing an improvement trend after a physician prescribed treatment.

Taken in the context of the entire specification, "correlating" means relating total homocysteine levels to cobalamin or folate deficiency,

a deficiency in both, or a deficiency in neither. In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship). The claim, in other words, provides that if the assay discloses "an elevated level of total homocysteine," the physician determines whether there is a cobalamin or folate deficiency by "correlating," i.e., comparing the elevated level with the normal homocysteine level. In sum, the specification and prosecution history confirm that the claim language "correlating,"in the

understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency. Further, the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms. The district court correctly construed the claim.

LabCorp also raises claim construction arguments in its challenge to the trial court's assessment of damages. Specifically, LabCorp contends that only twenty percent of the assays have elevated levels of homocysteine and therefore only this percentage could form the basis for a damages award. As noted earlier, LabCorp itself urged the district court to define "correlating" to include either a mutual or a reciprocal relationship. In the damages calculation, however, LabCorp prefers to restrict the claim to correlations that yield mutual relationships while excluding any reciprocal relationships. This court declines the invitation to apply a different claim construction for computation of damages than for infringement liability.

As explained above, the mutual relationship is established when an elevated homocysteine level is present, whereas a reciprocal relationship is established when an elevated homocysteine level is absent. LabCorp's new damages argument, in essence, attempts to change its claim construction position to read out the reciprocal relationship that it initially urged. This court, as it does now, has previously declined such invitations. *Interactive Gift Express*, 256 F.3d at 1346 (Fed. Cir. 2001) ("[A] party will be judicially estopped from asserting a position on appeal that is inconsistent with a position it advocated at trial and persuaded the trial court to adopt."). For all purposes in this litigation, this court affirms the district court's construction of the "correlating" step.

Direct Infringement

[2] The jury found LabCorp liable for indirect infringement. The record must show the presence of direct infringement, however, to support the verdict of indirect infringement. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 [28 USPQ2d 1378] (Fed. Cir. 1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement."). Thus, this court must examine whether there is substantial evidence in the record of the physicians' direct infringement. In that respect, the parties hinge the direct infringement issue solely on whether the physicians perform the correlating step.[1] Hence, we review the record for substantial evidence of that step.

---

[1] This court, therefore, does not address the assaying step.

Substantial evidence supports the jury's verdict. The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing. LabCorp's Discipline Director, Dr. Peter Wentz, testified that the physicians receiving total homocysteine assays from LabCorp carry out the correlating step.[2] Specifically, Dr. Wentz testified that "the correlating step... [is] a separate, distinct step that's performed by the physician who receives...our results." Inventor Dr. Sally Stabler also testified that it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency.

---

[2] Peter Wentz has a doctoral, not a medical, degree.

To support the verdict, the record does not need to contain direct evidence that every physician

performed the "correlating" step. "It is hornbook law that direct evidence of a fact is not necessary. 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 [229 USPQ 805] (Fed. Cir. 1986)(citing *Michalic v.*

Cleveland Tankers, Inc., 364 U.S. 325, 330 (1960)). As discussed above, the record contains sufficient circumstantial evidence to permit the jury to imply that physicians directly infringe.

Active Inducement

Section 271(b) of title 35 provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b)(2000). Although not express in the statute, this section requires proof of intent to induce infringement. *See, e.g., Hewlett Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 [15 USPQ2d 1525] (Fed. Cir. 1990) ("proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement"). A patentee may prove such intent through circumstantial evidence, much like direct infringement as discussed above. *See Water Techs. v. Calco, Ltd.*, 850 F.2d 660, 668 [7 USPQ2d 1097] (Fed. Cir. 1988)(noting that "circumstantial evidence may suffice" in proving intent).

The record contains such evidence of intent. LabCorp's own publications supply much of this evidence. LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.

Faced with these statements, LabCorp attempts to explain that these articles focus on heart disease rather than vitamin deficiency. As noted earlier, the patent does not require a correlation to some particular medical condition, but to a vitamin deficiency. The publications advocate use of the assay to identify a need for cobalamin/folate supplements. Thus, the vitamin deficiency remains the focus of the assay and the treatment (i.e., vitamin supplements).

Accordingly, a reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency. Moreover, the publications recommend treatment of this deficiency with vitamin supplements. Because "[i]ntent is a factual determination particularly within the province of the trier of fact," *Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1557[5 USPQ2d 1769](Fed. Cir. 1988), this court sees no reason to disturb the jury's finding regarding LabCorp's intent. Therefore, this court affirms the finding of indirect infringement based on the inducement analysis. This court declines to consider contributory infringement.

Invalidity

[3] A patent issued from the United States Patent and Trademark Office (PTO) bears the presumption of validity under 35 U.S.C. § 282. An accused infringer, therefore, must prove patent invalidity under the clear and convincing evidentiary standard. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272 [54 USPQ2d 1673] (Fed. Cir. 2000). LabCorp argues that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness. Likewise, LabCorp contends that claim 18, directed to the panel test, is also invalid on grounds of indefiniteness, and lack of written description and enablement.

Claim 13

First, LabCorp contends that the "correlating" step in claim 13 is indefinite. 35 U.S.C. § 112, second paragraph, provides: "The specification shall conclude with one or more claims particularly pointing out

and distinctly claiming the subject matter which the applicant regards as his invention."35 U.S.C. § 112, ¶ 2 (2000). The requirement to "distinctly"claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 [57 USPQ2d 1293](Fed. Cir. 2001); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547 [221 USPQ 1] (Fed. Cir. 1984). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 [60 USPQ2d 1272](Fed. Cir. 2001). In this case, as already noted, the claim construction exercise at the trial court produced a discernible and clear meaning. No "material ambiguities"

cloud the meaning of "correlating" to the extent that one of skill in the art would find the claim wholly indefinite. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 [64 USPQ2d 1945] (Fed. Cir. 2002) ("Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness."). This court affirms the trial court's denial of JMOL on this ground.

LabCorp next argues that the specification does not adequately describe the claimed invention under 35 U.S.C. § 112, first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same ....

35 U.S.C. § 112, ¶ 1. This language contains both the written description and enablement tests for sufficiency of the specification's disclosure.

With regard to the written description test, this court has previously explained, "the test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." *Moba*, 325 F.3d at 1320 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 [19 USPQ2d 1111](Fed. Cir. 1991)). As in the claim construction section above, this court assesses the written description possession test "from the viewpoint of one of skill in the art." *Moba*, 325 F.3d at 1321. The record is replete with evidentiary support that physicians in homocysteine research, i.e., persons of ordinary skill in the art, understood from the specification that the '658 patent inventors possessed the "correlating"step at the time they filed the patent application. For example, the examiner suggested the word "correlating" to the '658 patentee, showing that the PTO read the specification to include that feature. Additionally, the record reflects that LabCorp's own expert and employees understood the meaning of "correlating." Accordingly, this court finds that substantial evidence supports the jury finding that claim 13 was adequately supported by the '658 patent's written description.

The specification also shows that the patentee enabled the claimed invention. In *Union Pacific*, this court held that a claim was not enabled because it did not disclose use of a "comparing" step. 236 F.3d at 691. However, in *Union Pacific*, the inventors "purposely excluded computer programming details" necessary to perform the "comparing"step. *Id.* at 690. In this case, the correlating step does not require computer technology or extensive computations. Instead, the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art. The correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step. The patentee did not conceal or fail to disclose this correlation, but instead featured it as the centerpiece of the invention. *See, e.g.*, '658 patent, col. 4, ll. 17-20 ("It has now been discovered that an elevated level of total homocysteine in tissues of warmblooded [sic] animals correlates both with cobalamin deficiency and with folic acid deficiency ...."); *id.* at col. 5, ll. 64-66 ("It has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue."); *id.* at col. 9, ll. 26-29 ("Homocysteine levels above these [previously specified] ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication.").

[4] The prior art reference (Refsum) does not anticipate claim 13 under 35 U.S.C. § 102. "A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim." *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 [60 USPQ2d 1423] (Fed. Cir. 2001) (citation omitted). At the outset, the Refsum article does not recite all of the claim 13 limitations. Thus, anticipation would have to rely on an inherent disclosure of undisclosed features, in this case, the "correlating"limitation.

> To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference,

and that it would be so recognized by persons of ordinary skill.

Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 [20 USPQ2d 1746] (Fed. Cir. 1991).

Refsum does disclose that total homocysteine should be used to investigate "perturbations of homocysteine metabolism in humans during disease or pharmacological interventions that affect metabolism of one-carbon compounds." Refsum, however, does not specifically mention cobalamin or folate deficiencies. Indeed, one of the '658 patent inventors, Dr. Stabler, testified that cobalamin and folate deficiencies constitute just such a perturbation that Refsum suggested warranted further investigation. Rather than necessarily containing the correlation between homocysteine and cobalamin or folate deficiencies, Refsum simply invites further experimentation to find such associations. An invitation to investigate is not an inherent disclosure. Construed most favorably for LabCorp, Refsum discloses no more than a broad genus of potential applications of its discoveries. A prior art reference that discloses a genus still does not inherently disclose all species within that broad category. *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262[9 USPQ2d 1962](Fed. Cir. 1989) ("Under [defendant's] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless....").

Moreover, the PTO considered Refsum in allowing the claims. The '658 patent itself discusses Refsum at length at column 6, lines 26-43 and the patent's second page cites Refsum as a reference. Where, as here, the PTO previously considered the prior art reference, LabCorp bears an even heavier burden to prove invalidity. *Hewlett-Packard*, 909 F.2d at 1467. ("This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." (citation omitted)). Accordingly, substantial evidence supports the jury's finding that Refsum does not anticipate claim 13 by inherency.

[5] The test of obviousness in 35 U.S.C. § 103 is the primary condition of patentability. Obviousness hinges on four factual findings: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." *Nat'l Steel Car, Ltd., v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 [69 USPQ2d 1641] (Fed. Cir. 2004). LabCorp posits that claim 13 is obvious in view of the Refsum article when combined with other references disclosing that partial homocysteine assays could help diagnose cobalamin or folate deficiency. First, as noted above in the anticipation analysis, the examiner considered the Refsum article and also considered all but one of the secondary references that LabCorp contends render the invention obvious in combination with Refsum. The one reference that the examiner did not consider is cumulative of the others. Thus, the heavy burden of proof in the anticipation case also applies to obviousness. *Hewlett-Packard*, 909 F.2d at 1467. Next, the secondary references do not refer to total homocysteine, but rather to homocystine, one of the four components of total homocysteine. Thus, these secondary references do not add considerably to the Refsum disclosure. Finally, even if the secondary references disclosed total homocysteine, the record does not contain evidence showing that one of skill in the art would have been motivated to combine the various references. *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372 [56 USPQ2d 1065] (Fed. Cir. 2000) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination."(quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d

1572, 1577 [221 USPQ 929] (Fed. Cir. 1984))). These points alone would suffice to support the jury verdict.

Beyond these points, however, the record contains evidence of objective indicia that support the jury's nonobviousness verdict. The record, for example, shows that skilled artisans were initially skeptical about the invention. *See Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1556 [2 USPQ2d 1396] (Fed. Cir. 1987) (initial skepticism of experts is relevant to nonobviousness). The record also shows that Metabolite has licensed the invention to eight companies. *In re Sernaker*, 702 F.2d 989, 996 [217 USPQ 1](Fed. Cir. 1983) (extensive licensing supports nonobviousness). Substantial evidence, therefore, supports the implied jury factual findings that support its legal conclusion that claim 13 is not obvious in light of the Refsum article and the cited secondary references.

In sum, this court rejects LabCorp's various attempts to invalidate claim 13. Accordingly, this court affirms the district court's denial of LabCorp's JMOL.

Claim 18

Unlike claim 13, which Metabolite specifically asserted in its motion for partial summary judgment, Metabolite also requested the district court to declare that claim 18 covers the panel test method. Specifically, Metabolite sought a declaration that LabCorp's panel test that determines which particular vitamin is deficient infringes claim 18. The district court granted Metabolite's motion for partial summary judgment, finding that "[c]laim 18 covers LabCorp's performance of the panel test." In turn, LabCorp challenged the validity of claim 18 at trial. Neither party disputes that LabCorp continues to pay royalties for the panel test that provides the capability to identify which of the two vitamins is deficient.

Before this court can reach the merits of LabCorp's validity challenge, however, it must first ascertain whether it has jurisdiction to consider this challenge. Subject matter jurisdiction is an inquiry that this court must raise *sua sponte*, even where, as here, neither party has raised this issue. *Textile Prods., Inc., v. Mead Corp.*, 134 F.3d 1481, 1485 [45 USPQ2d 1633] (Fed. Cir. 1998) ("Every federal appellate court has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review,' even though the parties are prepared to concede it." (quotation omitted)); *see also Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 [70 USPQ2d 1087] (Fed. Cir. 2004) ("Any party or this court *sua sponte* may raise the question of subject matter jurisdiction.").

Although not as common as the scenario in which the alleged infringer seeks declaratory judgment against the patentee, it is possible for a patentee to also seek a declaratory judgment against a future infringer. *See Lang v. Pac. Marine & Supply Co., Ltd.*, 895 F.2d 761, 763[13 USPQ2d 1820](Fed. Cir. 1990) (noting that patentees seeking declaratory judgments against future infringers are rare, yet permissible). In order to demonstrate that an actual case or controversy exists, however, a patentee must demonstrate two elements. First, the patentee must show that the future infringer is "engaged in an activity directed to making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a)." *Lang*, 895 F.2d at 764. The patentee must then demonstrate that the defendant's acts represent a refusal to alter its course of action in light of the patentee's warning actions. *Id.*

[6] The facts of this case, however, demonstrate that there is no real case or controversy regarding the LabCorp panel test, alleged to infringe claim 18. Neither party disputes that the license is still in effect as to the panel tests that LabCorp performs. This license is, in essence, a licensor's covenant not to sue the licensee. *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1346 [60 USPQ2d 1291] (Fed. Cir. 2001) (citation omitted). In turn, this court has held that a covenant not to sue deprives a court of declaratory judgment jurisdiction. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855[50 USPQ2d 1304](Fed. Cir. 1999) (citing *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 [35 USPQ2d 1139] (Fed. Cir. 1995)). Accordingly, a licensor who has implicitly covenanted not to sue a

licensee by virtue of the license agreement itself cannot seek a declaratory judgment of infringement. Moreover, in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for which it continues to pay royalties. *Cf. Gen-Probe Inc.*, 359 F.3d at 1382 (holding that a licensee who continued paying royalties to the licensor did not have sufficient apprehension of suit giving rise to declaratory judgment subject matter jurisdiction). The district court's opinion concerning the panel test's infringement of claim 18 was merely advisory. Accordingly, the district court lacked subject matter jurisdiction, and this court vacates that portion of the district court's judgment.

Breach of contract

The interpretation of a contract is a matter of state law. *Power Lift, Inc. v. Weatherford Nipple-Up Sys., Inc.*, 871 F.2d 1082, 1085[10 USPQ2d 1464](Fed. Cir. 1989). A license agreement is at its core a contract. In this case, both parties agree that New Jersey law governs their rights and obligations under the license, including the termination clause. Under New Jersey law, breach of contract is a question of fact properly reserved for a jury. *Magnet Res., Inc. v. Summit MRI, Inc.*, 723 A.2d 976, 982 (N.J. Super. Ct. App. 1998). Thus, the standard of review for this court is

whether substantial evidence supports the jury's finding.

The jury found that "LabCorp breached the license agreement by terminating it" for the Abbott test. LabCorp contends that it did not formally terminate the contract, because the contract requires that the licensee provide written notice. The record contains no evidence of a written termination. The record does show, however, that LabCorp stopped paying royalties on the total homocysteine tests. Refusal to pay royalties is a material breach of the license. *See Dow Chem. Co. v. United States*, 226 F.3d 1334, 1346 [56 USPQ2d 1014](Fed. Cir. 2000). A material breach, in turn, constitutes termination even where the license agreement termination clause does not expressly so provide. *See Apex Pool Equip. Corp. v. Lee*, 419 F.2d 556, 562 (2d Cir. 1969) (holding that a licensee's material breach implicitly gives rise to a licensor's right to terminate); *see also Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 217 F.3d 8, 10(1st Cir. 2000) ("Every contract involves a bargained-for exchange of obligations, the material breach of which by one party gives the other party a right to terminate."); Restatement (Second) of Contracts § 237(1981). This court, therefore, affirms the jury's finding that LabCorp breached the license agreement.

Enhanced damages

LabCorp does not directly challenge the jury's willfulness finding. Instead, LabCorp contends that the district court did not discuss the *Read* factors for enhanced damages. *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 [23 USPQ2d 1426] (Fed. Cir. 1992), *abrogated in part on other grounds, Markman*, 52 F.3d at 975. This court, therefore, addresses only the district court's grant of enhanced damages.

To be sure, this court has enunciated its strong preference that a district court set forth its rationale for an award of enhanced damages to facilitate appellate review. *Read*, 970 F.2d at 828 ("To enable appellate review, a district court is obligated to explain the basis for the award, particularly where the maximum amount is imposed."). On the other hand, this court has also recognized the competing public policy of conserving judicial resources and has cautioned that a remand is a "step not taken lightly." *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 814 [15 USPQ2d 1481](Fed. Cir. 1990) (holding that a remand "should be limited to cases in which further action must be taken by the district court or in which the appellate court has no way open to it to affirm or reverse the district court's action under review"). As this court found in *Consolidated Aluminum*, "an appellate court need not close its eyes to the record where, as in this case, there is a way clearly open to affirm the district court's action." *Id.* at 814. Accordingly, this court considers the findings in the record for an abuse of discretion in doubling the infringement damages.

[7] First, this court considers the second *Read* factor, namely whether LabCorp conducted an investigation regarding the scope of the '658 patent in order to form a good-faith belief. *Read Corp.*, 970

F.2d at 827. LabCorp concedes that Dr. Wentz alone determined that the Abbott total homocysteine tests did not infringe the '658 patent and therefore LabCorp would not need to continue paying royalties to Metabolite. Dr. Wentz himself testified during trial that his determination that the '658 patent did not extend to the Abbott total homocysteine tests was based solely on his interpretation of the license agreement between LabCorp and Metabolite. Moreover, Dr. Wentz testified that he did not consult the '658 patent itself. He also conceded his lack of training in patent law. Based on this evidence alone, the district court could easily have determined that LabCorp did not conduct a reasonable investigation into potential infringement by the Abbott total homocysteine tests. *See Underwater Devices Inc. v. Morrison-Knudsen Co., Inc.*, 717 F.2d 1380, 1390[219 USPQ 569](Fed. Cir. 1983) (affirming district court's grant of enhanced damages where defendant obtained incompetent opinion from in-house counsel who was not a patent attorney, did not consult the patent file histories, and prepared a memo containing "only bald, conclusory and unsupported remarks regarding validity and infringement of the [] patents").

LabCorp's failure to conduct a reasonable and independent investigation regarding the Abbott total homocysteine test is further highlighted by the very terms of the license agreement between LabCorp and Abbott Labs. In the license agreement, Abbott Labs specifically excludes the '658 patent from a warranty covered by an indemnity provision. The warranty specifically excludes:

> [A]ny claim of infringement which may arise under the subject matter of U.S. Patent 4,940,658 and any U.S. or foreign patents claiming priority therefrom or otherwise related thereto. *Except with respect to the foregoing* and at the time of signing this Agreement, Abbott has no reasonable knowledge of any infringement of third party patent rights that would arise from the use of the Imx Homocysteine Research Assay.

(emphasis added). By accepting this provision, LabCorp knew or should have known that Abbott Labs believed the use of the Abbott test might infringe the '658 patent. This language in the license agreement would have put a reasonable licensee on notice to conduct its own investigation regarding the '658 patent coverage of the Abbott total homocysteine test.

In addition to the second *Read* factor, the record also reflects that LabCorp is a large company with extensive financial means, i.e., *Read* factor four. LabCorp's infringing activities of claim 13 began in 1998 without any attempts to remedy the infringement, *Read* factors six and seven, respectively. The district court therefore had evidence before it warranting consideration of at least four *Read* factors.

That the district court did not explicitly set forth its rationale for awarding Metabolite enhanced damages based on LabCorp's willful indirect infringement is not fatal to its decision. As in *Consolidated Aluminum*, "[n]o useful purpose would be served by a remand to enable the district court to tell [this court] in express terms what [it] already know[s] from the record."910 F.2d at 815. On the basis of the appellate record, this court can readily discern at least four *Read* factors that the district court likely considered when using its discretion to double the infringement damages. Accordingly, this court holds that the district court did not abuse its discretion in enhancing the infringement damages. The district court's failure to discuss the *Read* factors, although contrary to this court's strong preference for the enumerated bases underlying its decision, in this case was at most harmless error.

Injunction

The district court granted Metabolite's motion "to enjoin LabCorp from performing 'any homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method.'"

LabCorp argues that the injunction is too broad because it extends beyond the scope of the claims. To the contrary, the injunction simply addresses LabCorp's specific acts constituting indirect infringement. LabCorp performs the assays upon request from physicians and in doing so indirectly infringes. The

district court correctly enjoined LabCorp from infringement. LabCorp also argues that the injunction is defective in form under the Federal Rules of Civil Procedure, because Rule 65(d) requires that a district court "set forth the reasons"for issuing an injunction. The district court's order states that it "finds no sound reason for denying the injunction." While this statement does not explicitly set forth detailed reasons, the district court properly granted the injunction because LabCorp was found to infringe. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 [6 USPQ2d 1277](Fed. Cir. 1988) ("[A]n injunction should issue once infringement has been established unless there is a sufficient reason for denying it."). The district court's brevity is not reversible error.

CONCLUSION

The district court did not err in denying JMOL, awarding enhanced damages, and granting the permanent injunction.

COSTS

Each party shall bear its own costs.

AFFIRMED

Concurring/Dissenting Opinion Text

Concurrence/Dissent By:

Schall, J., concurring-in-part, dissenting-in-part.

I agree with the majority's conclusions with respect to validity, the absence of a case or controversy regarding infringement of claim 18, breach of contract, enhanced damages, and the district court's injunction. However, I respectfully dissent from the majority's construction of claim 13 of the '658 patent. Because I think claim 13 covers only the correlation of elevated levels of homocysteine, I would remand the case for a recalculation of the damages resulting from indirect infringement.

Claim 13 of the '658 patent is an independent claim for a two-step method:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Col. 41, ll. 58-65. Proper construction of the terms "correlating"and "elevated" is dispositive of the issue of infringement of claim 13. The district court construed "elevated" to mean "raised above the normal range," and "correlating" as "to establish a mutual or reciprocal relationship between." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-Z-870, slip op. at 2-3 (D. Colo. Nov. 29, 2000) (*Markman Order*). Disagreeing with neither of these constructions, the majority holds that when a patient's homocysteine level is not "elevated," claim 13 may nevertheless be infringed because "correlating" includes establishing both a mutual relationship and a reciprocal_relationship. The majority states:

> In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither(i.e., a reciprocal relationship) .... [T]he specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency.

In my view, the majority impermissibly expands the scope of claim 13 beyond the actual words of the claim.

I begin with what I see as the controlling principles of claim construction. When interpreting the claims of a patent, the court should look first to the intrinsic evidence of record: the claim, the specification, and, if in evidence, the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 [39 USPQ2d 1573] (Fed. Cir. 1996). There exists within the intrinsic evidence a "hierarchy of analytical tools." *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344[47 USPQ2d 1418](Fed. Cir. 1998). First, the language of the claim should be considered—"[t]he actual words of the claim are the controlling focus." *Id.* The claim language defines the bounds of claim scope. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 619-20 [34 USPQ2d 1816](Fed. Cir. 1995). Because the claims define the patentee's right to exclude others, "the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim." *Renishaw plc v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248[48 USPQ2d 1117](Fed. Cir. 1998).

If the meaning of a claim term is clear on its face, consideration of the remaining intrinsic evidence is restricted to determining if a deviation from the clear language of the claim is specified. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 [59 USPQ2d 1401] (Fed. Cir. 2001). The court may consider the patent specification in construing whether the patentee has intended for the meaning of a claim term to deviate from its ordinary meaning. *Vitronics*, 90 F.3d at 1582. The court may also consider the prosecution history, if it is in the record, for evidence of an intentional deviation from the plain meaning of a claim term. *Id.*

Beginning with the ordinary meaning of the claim terms, I too do not disagree with the district court's construction of the terms "elevated" and "correlating."Nor do I disagree with the majority's conclusion that the claim language does not require a further association between the level of total homocysteine and either a hematologic or neuropsychiatric abnormality or both. I cannot agree with the majority, however, that claim 13 is infringed when the test demonstrates that a patient's homocysteine level is *not* "elevated."The plain language of the claim requires "elevated" levels of homocysteine, and a heavy presumption weighs in favor of the ordinary and customary meaning of that term. *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1366 [62 USPQ2d 1658] (Fed. Cir. 2002). As the district court properly construed the term, "elevated" requires a level of homocysteine that is "raised above the normal range." *Markman Order*, slip op. at 2-3. Thus, for claim 13 to be infringed, the homocysteine assay must evince a level of homocysteine that is raised above the normal range. In short, in my view the majority

disregards the explicit limitation in claim 13 that only an "elevated" level of homocysteine can be "correlated"with a vitamin deficiency.

There is no language in claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency. Ordinary meaning thus dictates that a patient's homocysteine level be "elevated" in order for a physician to practice claim 13. If the patient's homocysteine levels are not "elevated," by the plain language of the claim, there is no "correlating" to be done. The language of claim 13 does not suggest that the claim encompasses the correlation of unelevated levels with the absence of a deficiency, for the introductory phrase claims "a method for detecting a deficiency," without addressing at all the detection of the absence of a deficiency. '658 patent, col. 41, ll. 58-59.

We have repeatedly stated that "[c]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." *Tex. Instruments Inc. v. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 [26 USPQ2d 1018](Fed. Cir. 1993) (quoting *Autogiro Co. v. United States*, 384 F.2d 391, 396 [155 USPQ 697] (Ct. Cl. 1967)); *Oak Tech., Inc. v. Int'l Trade Comm'n*, 248 F.3d 1316, 1329 [58 USPQ2d 1748] (Fed. Cir. 2001). In this case, however, the majority has permitted claim 13 to be infringed even when homocysteine assays result in unelevated levels. The majority thereby broadens claim 13 to also include, although it is not expressly claimed, correlating unelevated levels of homocysteine with the absence of a vitamin deficiency.

Relying on language from the specification and the prosecution history, the majority brings assays that demonstrate unelevated levels of homocysteine within the province of claim 13 by focusing its construction on the term "correlating."The problem I have with this approach is that it ignores the term "elevated."In addition, because the term "elevated" in claim 13 is unambiguous on its face, the specification and prosecution history of the '658 patent may be consulted only to determine if the patentee intended to deviate from ordinary meaning. *Interactive Gift Express*, 256 F.3d at 1331. There is no evidence before us that any deviation was intended. Throughout the specification, the term "elevated" is consistently used to refer to levels that are raised above average. For example, the specification explains that

> The normal range for homocysteine in human serum is from about 7 to about 22 ?mol/liter. *Homocysteine levels above these ranges* are indicative of cobalamin and/or folate deficiency ....
>
> * * * *
>
> When homocysteine levels are *elevated* in individuals without inherited defects, at least one of folate or cobalamin is deficient.

'658 patent, col. 9, ll. 23-29, 38-40(emphases added). Nor is there any evidence from the prosecution history that the patentee relinquished this claim construction in an amendment or in an argument to overcome or distinguish a prior art reference. *Vitronics*, 90 F.3d at 1582. Accordingly, I construe Claim 13 to require an assay that demonstrates an "elevated" homocysteine level, or one "raised above the normal range," in order for the claim to be practiced.

Pursuant to this claim construction, claim 13 is only infringed when the assays performed by LabCorp reveal elevated levels of homocysteine. As LabCorp explains, and as Metabolite does not dispute, approximately eighty to eighty-four percent of the assays LabCorp processes reveal unelevated levels of homocysteine. I would therefore vacate the jury's verdict that the assays resulting in unelevated levels of homocysteine infringed claim 13, and further vacate and remand the jury's verdict on damages for recalculation based only on those infringing assays that demonstrate elevated levels of homocysteine.

- End of Case -